Wisconsin Department of Safety and Professional Services
Division of Policy Development
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Tony Evers, Governor
Dawn Crim, Secretary

VIRTUAL/TELECONFERENCE
HEARING AND SPEECH EXAMINING BOARD
Virtual, 4822 Madison Yards Way, Madison
Contact: Tom Ryan (608) 266-2112
January 10, 2022

The following agenda describes the issues that the Board plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. Please consult the meeting minutes for a record of the actions of the Board.

AGENDA

1:00 P.M.

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. **Adoption of Agenda (1-3)**

B. **Approval of Minutes of October 4, 2021 (4)**

C. Reminders: Conflicts of Interest, Scheduling Concerns

D. **Introduction, Announcements, and Recognition**
   1) Introduction of Jason Meyer, Audiologist Member (Succeeds: Johnson) – 7/1/2025

E. **Administrative Matters**
   1) Department, Staff and Board Updates
   2) Annual Policy Review **(5-8)**
   3) Election of Officers, Appointment of Liaisons and Alternates, and Delegation of Authorities **(9-16)**
   4) Board Members – Term Expiration Dates
      a. Broeckert, Robert R. – 7/1/2024
      b. Harris, Michael S. – 7/1/2023
      c. Kanter, Catherine D. – 7/1/2024
      d. Klapperich, Steven J. – 7/1/2019
      e. Krier, Thomas J. – 7/1/2021
      f. Meyer, Jason J. – 7/1/2025
      g. Pazak, Kathleen A. – 7/1/2023
      h. Pirrello, Mary – 7/1/2024
      i. Seligman, David H. – 7/1/2023
      j. Willemon, Justen J. – 7/1/2025

F. Legislative and Policy Matters – Discussion and Consideration

G. **Administrative Rule Matters – Discussion and Consideration (17)**
   1) Review Preliminary Rule Draft – HAS 4 and 6, Relating to Audiometric Testing and Reciprocal Licensure **(18-29)**
   2) Pending or Possible Rulemaking Projects **(30)**

H. **Federal Drug Administration (FDA) Proposed Rules on Over-the-Counter Hearing Aids – Discussion and Consideration (31-118)**

I. **School and Medical Facility Caseload – Discussion and Consideration (119)**

J. **COVID-19 – Discussion and Consideration**

K. Discussion and Consideration of Items Added After Preparation of Agenda:
   1) Introductions, Announcements and Recognition
   2) Nominations, Elections, and Appointments
   3) Administrative Matters
   4) Election of Officers
   5) Appointment of Liaisons and Alternates
   6) Delegation of Authorities
   7) Education and Examination Matters
   8) Credentialing Matters
   9) Practice Matters
   10) Legislative and Policy Matters
   11) Administrative Rule Matters
   12) Liaison Reports
   13) Board Liaison Training and Appointment of Mentors
   14) Informational Items
   15) Division of Legal Services and Compliance (DLSC) Matters
   16) Presentations of Petitions for Summary Suspension
   17) Petitions for Designation of Hearing Examiner
   18) Presentation of Stipulations, Final Decisions and Orders
   19) Presentation of Proposed Final Decisions and Orders
   20) Presentation of Interim Orders
   21) Petitions for Re-Hearing
   22) Petitions for Assessments
   23) Petitions to Vacate Orders
   24) Requests for Disciplinary Proceeding Presentations
   25) Motions
   26) Petitions
   27) Appearances from Requests Received or Renewed
   28) Speaking Engagements, Travel, or Public Relation Requests, and Reports

L. **Public Comments**

CONVENE TO CLOSED SESSION to deliberate on cases following hearing (s. 19.85(1)(a), Stats.); to consider licensure or certification of individuals (s. 19.85(1)(b), Stats.); to consider closing disciplinary investigations with administrative warnings (ss. 19.85 (1)(b), and 440.205, Stats.); to consider individual histories or disciplinary data (s. 19.85(1)(f), Stats.); and to confer with legal counsel (s. 19.85(1)(g), Stats.)

M. Deliberation of Items Added After Preparation of the Agenda:
   1) Education and Examination Matters

2) Credentialing Matters
3) DLSC Matters
4) Monitoring Matters
5) Professional Assistance Procedure (PAP) Matters
6) Petitions for Summary Suspensions
7) Petitions for Designation of Hearing Examiner
8) Proposed Stipulations, Final Decisions and Orders
9) Proposed Interim Orders
10) Administrative Warnings
11) Review of Administrative Warnings
12) Proposed Final Decisions and Orders
13) Matters Relating to Costs/Orders Fixing Costs
14) Case Closings
15) Board Liaison Training
16) Petitions for Assessments and Evaluations
17) Petitions to Vacate Orders
18) Remedial Education Cases
19) Motions
20) Petitions for Re-Hearing
21) Appearances from Requests Received or Renewed

N. Consulting with Legal Counsel

RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

O. Vote on Items Considered or Deliberated Upon in Closed Session if Voting is Appropriate

P. Open Session Items Noticed Above Not Completed in the Initial Open Session

Q. License Ratification – Discussion and Consideration

ADJOURNMENT

NEXT MEETING: APRIL 11, 2022

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MEETINGS AND HEARINGS ARE OPEN TO THE PUBLIC, AND MAY BE CANCELLED WITHOUT NOTICE.

Times listed for meeting items are approximate and depend on the length of discussion and voting. All meetings are held at 4822 Madison Yards Way, Madison, Wisconsin, unless otherwise noted. In order to confirm a meeting or to request a complete copy of the board's agenda, please call the listed contact person. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of disciplinary hearings may be changed by the examiner for the convenience of the parties. Requests for interpreters for the deaf or hard of hearing, or other accommodations, are considered upon request by contacting the Affirmative Action Officer, 608-266-2112, or the Meeting Staff at 608-266-5439.

VIRTUAL/TELECONFERENCE
HEARING AND SPEECH EXAMINING BOARD
MEETING MINUTES
OCTOBER 4, 2021

PRESENT: Robert Broeckert, Barbara Johnson, Catherine Kanter, Steven Klapperich, Kathleen Pazak, Mary Pirrello, Justen Willemon

EXCUSED: Michael Harris, Thomas Krier, David Seligman

STAFF: Tom Ryan, Executive Director; Jon Derenne, Legal Counsel; Nilajah Hardin, Administrative Rule Coordinator; Katlin Schwartz, Bureau Assistant; Kimberly Wood, Program Assistant Supervisor-Adv.; and other Department Staff

CALL TO ORDER

Robert Broeckert, Chairperson, called the meeting to order at 1:12 p.m. A quorum was confirmed with seven (7) members present.

ADOPTION OF AGENDA

MOTION: Barbara Johnson moved, seconded by Catherine Kanter, to adopt the Agenda as published. Motion carried unanimously.

APPROVAL OF MINUTES OF JULY 12, 2021

MOTION: Barbara Johnson moved, seconded by Steven Klapperich, to approve the Minutes of July 12, 2021 as published. Motion carried unanimously.

INTRODUCTIONS, ANNOUNCEMENTS, AND RECOGNITION

MOTION: Robert Broeckert moved, seconded by Catherine Kanter, to recognize and thank Barbara Johnson for her years of dedicated service to the Board and State of Wisconsin. Motion carried unanimously.

LICENSE RATIFICATION

MOTION: Steven Klapperich moved, seconded by Justen Willemon, to delegate authority to the Chairperson to ratify the scores from the October 4, 2021 examinations and to grant the licenses once requirements are met. Motion carried unanimously.

ADJOURNMENT

MOTION: Robert Broeckert moved, seconded by Catherine Kanter, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 1:36 p.m.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request:	2) Date when request submitted:
Kimberly Wood, Program Assistant Supervisor-Adv. on behalf of Division of Policy Development Executive Directors	12/13/2021 Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting

3) Name of Board, Committee, Council, Sections:

All Boards

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
First Meeting of 2022	☒ Yes ☐ No	Annual Policy Review

7) Place Item in:	8) Is an appearance before the Board being scheduled?	9) Name of Case Advisor(s), if applicable:
☒ Open Session ☐ Closed Session	☐ Yes ☒ No	N/A

10) Describe the issue and action that should be addressed:

Please be advised of the following Annual Policy Review items:

1. Attendance/Quorum: Thank you for your service and for your commitment to meeting attendance. If you cannot attend a meeting or if you have scheduling conflicts impacting your attendance, please let us know ASAP. Timely notification is appreciated as quorum is required for our Boards, Sections and Councils to meet pursuant to Open Meetings Law.
2. Walking Quorum: Board/Section/Council members must not collectively discuss the body's business outside of a properly noticed meeting. Should several members of a body do so, the members could be violating the open meetings law.
3. Agenda Deadlines: Please communicate agenda topics to your Executive Director before the agenda submission deadline which is at 12:00 pm, 8 business days prior to a meeting. (Attachment: Timeline of a Meeting)
4. Travel Voucher and Per Diem Submissions: Please submit all Per Diem and Reimbursement claims to DSPS within 30 days of the close of each month in which expenses are incurred. (Attachments: Per Diem Example, Travel Voucher Example)
5. Lodging Accommodations/Hotel Cancellation Policy: Lodging accommodations are available to eligible members. Standard eligibility: member must leave home before 6:00 a.m. to attend a meeting by the scheduled start time.
   - If a member cannot attend a meeting it is their responsibility to cancel their reservation within the applicable cancellation timeframe. If a meeting is changed to occur remotely or is cancelled or rescheduled DSPS staff will cancel or modify reservations as appropriate.
6. Inclement Weather Policy: In the event of inclement weather the agency may change a meeting from an in-person venue to one that is executed remotely.

11) Authorization

Kimberly Wood	12/13/2021
Signature of person making this request	Date
Supervisor (Only required for post agenda deadline items)	Date
Executive Director signature (Indicates approval for post agenda deadline items)	Date

Directions for including supporting documents:

1. This form should be saved with any other documents submitted to the Agenda Items folders.
2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.
3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.

Timeline of a Meeting

8 business days prior to the meeting: All agenda materials are due to the Department by 12:00 pm, 8 business days prior to the meeting date.

7 business days prior to the meeting: The draft agenda page is due to the Executive Director. The Executive Director transmits to the Chair for review and approval.

5 business days prior to the meeting: The approved agenda is returned to the Bureau Assistant for agenda packet production and compilation.

4 business days prior to the meeting: Agenda packets are posted on the DSPS Board SharePoint site and on the Department website.

Agenda Item Examples:

- Approval of the Agenda and Minutes (from the last meeting)
- Open Session Items
  - Public Hearings (on Admin Rules)
  - Administrative Matters
  - Legislation and Policy Matters
  - Administrative Rules Matters
  - Credentialing Matters
  - Education and Exam Issues
  - Public Agenda Requests
  - Current Issues Affecting the Profession
  - Public Comments
- Closed Session items
  - Deliberations on Proposed Disciplinary Actions
    - Stipulations
    - Administrative Warnings
    - Case Closings
    - Monitoring Matters
    - Professional Assistance Procedure (PAP) Issues
  - Proposed Final Decisions and Orders
  - Orders Fixing Costs/Matters Relating to Costs
  - Credentialing Matters
  - Education and Exam Issues

Thursday of the Week Prior to the Meeting: Agendas are published for public notice on the Public Notices and Meeting Minutes website: **publicmeetings.wi.gov**.

1 business day after the Meeting: "Action" lists are distributed by staff detailing board actions on closed session business.

5 business days after the Meeting: "To Do" lists are distributed to staff to ensure that board decisions are acted on and/or implemented within the appropriate divisions in the Department. Minutes approved by the board are published on the Department's website.

Department of Safety and Professional Services

PER DIEM REPORT

INSTRUCTIONS: Claimant records board-related activities by entering the date of an activity, the duration of time spent in that activity, the relevant purpose code (see purpose code descriptions below), where the activity is conducted, and the type of activity performed. Only one (1) $25.00 per diem payment can be issued on any given calendar day.

Purpose Codes:

A. **Official meetings including video/teleconference calls** (automatic day of per diem)**:** i.e., board, committee, board training or screening panels; **Hearings,** i.e., Senate Confirmation, legislative, disciplinary or informal settlement conferences; **Examinations and Test Development Sessions,** i.e., test administration, test review or analysis events, national testing events, tour of test facilities, etc.)

B. **Other** (One (1) per diem will be issued for every five (5) hours spent in category B, per calendar month): i.e., review of disciplinary cases, consultation on cases, review of meeting materials, board liaison work e.g., contacts regarding Monitoring, Professional Assistance Procedure, Credentialing, Education and Examinations

NAME OF EXAMINING BOARD OR COUNCIL	BOARD OR COUNCIL MEMBER'S NAME
EXAMPLE EXAMINING BOARD	**MARY SUNSHINE**

Activity Date **MM/DD/YY**	Duration of Activity **Hours/Minutes**	Purpose Code **A or B**	Where Performed **City/Location (Home, Work, DSPS)**	Activity **Describe Activity Performed (see purpose codes)**
12/2/20	**2 hrs**	**B**	**Pleasant Prairie/Home**	**Review of screening panel materials**
12/3/20	**2 hr / 30 mins**	**B**	**Pleasant Prairie/Home**	**Review of screening panel materials**
12/10/20	1 hr	A	Pleasant Prairie/Home	Screening Panel Meeting - Teleconference
12/12/20	**1 hr / 30 mins**	**B**	**Pleasant Prairie/Home**	**Case consultation**
12/13/20	**1 hr**	**B**	**Pleasant Prairie/Home**	**Liaison: Application Review**
12/16/20	6 hrs	A	Madison/DSPS	Board Member Training

The 5-hour rule applies to "B" code activities. Add the 'B' codes within the calendar month and then divide by five (5) hours to calculate your per diem payment. In this case the total is seven (7) hours which equals one (1) day of per diem.

Each 'A' code is an automatic day of per diem regardless of time spent in that activity. Ms. Sunshine is eligible for two (2) additional days of payment.

Department staff completes the fields titled "Total Days Claimed".

CLAIMANT'S CERTIFICATION

The undersigned certifies, in accordance with § 16.53, Wis. Stats., that this account for per diem, is just and correct; and that this claim is for service necessarily incurred in the performance of duties required by the State, as authorized by law.

Comments:

Mary Sunshine 1/4/2021

Claimant's Signature Date

Supervisor Date

EMPL ID: 100012345-0

To be completed by Department staff: **TOTAL DAYS CLAIMED:** 3 @ $25.00 = 75.00

State of Wisconsin

Travel Voucher

DOCUMENT NUMBER TL

For Agency Use Only

Staple Receipts Face Up On Backside

Safety & Professional Services

Department/ Division Example Examining Board

State Officer/Employee Name Mary Sunshine

Mo/Yr **From/To:**

Emp ID 100012345 **Z**

Address 2424 Happy Road

City Pleasant Prairie **State** WI **Zip-Code** 53158

FY	FUND	BUSINESS UNIT	DEPART	APPR CLASS	OBJECT	PROJECT			BALANCE SHEET ACCT	REPORTING CATEGORY	PROJECT NUMBER	AMOUNT DEBIT	AMOUNT CREDIT
2021	10000	16500	1651300200	12100	7340000	16500P1<BRD ID>							
				12800		16500P2<TRD ID>							
				22100									
											TOTALS		

Official Business		Travel Points		HDQS-TIME		Personal Vehicle		Meals, including tips			Other Allowable Expenses		Total Allowable Expenses	
Date	Purpose of Trip	From	To	Depart	Return	Miles	Lodging	Morning	Noon	Evening	Item	Amount	Taxable	Non-Taxable
Use	Board Meeting	Home base	Madison	Report times you left		Miles	P-card	$8.00	$10.00	$20.00			Report	Report
separate		Madison	Home base	and returned home if		must be		Maximum in-state amounts					meal cost	meal cost
lines for	You must identify			meals are claimed		split.	Enter		or				here if there	here if there
each leg	the purpose of					Cannot	"P-card"	$10.00	$15.00	$25.00			is **NO**	**IS** an
of your	your trip.					place	when hotel	Maximum out-of-state amounts					overnight	overnight
trip.						roundtrip	is provided						stay.	stay.
						total on	by DSPS	Must leave	Must leave	Must return				
						one line.		home	home	home after				
								before	before	7:00 p.m.				
								6:00 a.m.	10:30 a.m.					
									and return					
									home after					
	LEGEND:	**Staff can fill in these areas.**							2:30 p.m.					
		Board Member MUST fill in these areas												
				Sub-Totals										

*Item billed directly to the state agency

			Mileage Costs
	Miles at	**0.510 cents/mile**	**Totals**
			Total Expenditure
			Less Travel Advance
			Net Amount Due

Claimant's Statement § 16.53 Wisconsin Statutes

I declare, under penalties, that all claimed travel expenses are true and correct and are in conformity with Wisconsin statute 16.53 and related agreements. This claim represents reasonable and actual expenses necessarily incurred by me personally in the performance of official duties and no portion was previously reimbursed to me by the State or any other source.

Date _____ **Claimant's Signature** _____

I certify that this travel claim is reasonable, proper, and in conformity with applicable statutes, travel schedule amounts, and/or collective bargaining agreements.

Date _____ **Supervisor's Signature** _____

I certify that all expenses on this voucher conform to statutory, departmental or applicable collective bargaining provisions, and were necessary in the official performance of duties required by the State Expenditures are determined to be reasonable and proper, and that sufficient funds are available to pay this claim.

_____

Agency Head or Authorized Representative

Audited in accordance with S. 16.53 Wisconsin Statutes and allowed by the provisions of chapter 20.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Katlin Schwartz, Bureau Assistant		**2) Date when request submitted:** 12/13/2021 **Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting**	
3) Name of Board, Committee, Council, Sections: Hearing and Speech Examining Board			
4) Meeting Date: 1/10/2022	**5) Attachments:** ☒ Yes ☐ No	**6) How should the item be titled on the agenda page?** Administrative Matters • Election of Officers, Appointment of Liaisons and Alternates, Delegation of Authorities	
7) Place Item in: ☒ Open Session ☐ Closed Session	**8) Is an appearance before the Board being scheduled?** ☐ Yes ☒ No	**9) Name of Case Advisor(s), if applicable:** N/A	

10) Describe the issue and action that should be addressed:

1) The Board, Council or Section should conduct Election Officers: Chairperson, Vice Chairperson & Secretary
2) The newly elected Chairperson should review and appoint/reappoint Liaisons and Alternates as appropriate
3) The Board should review and then consider its existing delegated authorities including any modification of these delegations and any proposals for additional delegations.
    a. Credentialing Delegations
    b. Monitoring Delegations
    c. Pre-Screening Delegations

11) Authorization

Katlin Schwartz	12/13/2021
Signature of person making this request	**Date**
Supervisor (Only required for post agenda deadline items)	**Date**
Executive Director signature (Indicates approval for post agenda deadline items)	**Date**

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HEARING AND SPEECH EXAMINING BOARD

2021 Elections, Liaison and Delegations

ELECTION RESULTS	
Chairperson	Robert Broeckert
Vice Chairperson	David Seligman
Secretary	Kathleen Pazak

LIAISON APPOINTMENTS	
Credentialing Liaison(s)	Robert Broeckert, Barbara Johnson, Steven Klapperich, Thomas Krier, Kathleen Pazak
Exam Liaison(s)	Robert Broeckert, Barbara Johnson, Steven Klapperich
Continuing Education (CE) Liaison(s)	Barbara Johnson, Thomas Krier
Professional Assistance Procedure (PAP) and Monitoring Liaison(s)	Robert Broeckert
Legislative Liaison(s)	Catherine Kanter
Travel Liaison(s)	Barbara Johnson
Website Liaison(s)	Robert Broeckert, Thomas Krier
Practice Questions Liaison(s)	Barbara Johnson, Catherine Kanter, Steven Klapperich
Screening Panel	**Team A:** Michael Harris, Steven Klapperich, David Seligman **Team B:** Robert Broeckert, Kathleen Pazak, David Seligman ***Alternates:*** Barbara Johnson, Thomas Krier

Delegation of Authorities

Document Signature Delegations

MOTION: Steven Klapperich moved, seconded by Michael Harris, to delegate authority to the Chairperson (or in absence of the Chairperson, the highest-ranking officer or longest serving board member in that succession) to sign documents on behalf of the Board in order to carry out its duties. Motion carried unanimously.

MOTION: Catherine Kanter moved, seconded by Steven Klapperich, in order to carry out duties of the Board, the Chairperson (or in absence of the Chairperson, the highest-ranking officer or longest serving board member in that succession) has the ability to delegate signature authority for purposes of facilitating the completion of assignments during or between meetings. The members of the Board hereby delegate to the Executive Director or DPD Division Administrator, the authority to sign on behalf of a board member as necessary. Motion carried unanimously.

Delegated Authority for Urgent Matters

MOTION: Kathleen Pazak moved, seconded by Barbara Johnson, that in order to facilitate the completion of urgent matters between meetings, the Board delegates its authority to the Chairperson (or, in the absence of the Chairperson, the highest-ranking officer or longest serving board member in that succession), to appoint liaisons to the Department to act in urgent matters. Motion carried unanimously.

Delegation to Chief Legal Counsel Due to Loss of Quorum

MOTION: Steven Klapperich moved, seconded by Barbara Johnson, to delegate the review of disciplinary cases to the Department's Chief Legal Counsel due to lack of/loss of quorum after two. consecutive meetings. Motion carried unanimously.

Monitoring Delegations

Delegation of Authorities for Monitoring

MOTION: Barbara Johnson moved, seconded by Kathleen Pazak, to adopt the "Roles and Authorities Delegated for Monitoring" document as presented in the January 11, 2021 agenda materials on pages 13-14. Motion carried unanimously.

Delegation of Authorities for Legal Counsel to Sign Monitoring Orders

MOTION: Steven Klapperich moved, seconded by Michael Harris, to delegate to Board Legal Counsel the authority to sign Monitoring orders that result from Board meetings on behalf of the Chairperson. Motion carried unanimously.

Credentialing Authority Delegations

Delegation of Authority to Credentialing Liaison(s)

MOTION: Barbara Johnson moved, seconded by Kathleen Pazak, to delegate authority to the Credentialing Liaison(s) to serve as a liaison between DSPS and the Board and to act on behalf of the Board in regard to credentialing applications or questions presented to them including the signing of documents related to applications except that potential denial decisions shall be referred to the full Board for final determination. Motion carried unanimously.

Delegation of Authority to DSPS When Credentialing Criteria is Met

MOTION: Catherine Kanter moved, seconded by Barbara Johnson, to delegate credentialing authority to the Department to act upon applications that meet all credentialing statutory and regulatory requirements without Board or Board liaison review. Motion carried unanimously.

Delegation of Authority for Predetermination Reviews

MOTION: Barbara Johnson moved, seconded by Steven Klapperich, to delegate authority to the Department Attorneys to make decisions regarding predetermination applications pursuant to Wis. Stat. § 111.335(4)(f). Motion carried unanimously.

Delegation of Authority for Conviction Reviews

MOTION: Barbara Johnson moved, seconded by Catherine Kanter, to delegate authority to the Department Attorneys to review and approve applications with convictions which are not substantially related to the practice of audiology and/or speech-language pathology. Motion carried unanimously.

Delegation of Authority for Reciprocity/Endorsement Reviews - Hearing Instrument Specialists Reviews

MOTION: Barbara Johnson moved, seconded by Michael Harris, to delegate authority to the Department Attorneys to review and approve reciprocity/endorsement applications in which the out-of-state license requirements for a hearing instrument specialist are equivalent to or higher than the Board's requirements, and such state or jurisdiction has a program equivalent to, or stricter than, the Board's requirements for determining whether applicants in this state are qualified to fit and sell hearing aids. Motion carried unanimously.

Delegation of Authority for Reciprocity/Endorsement Reviews - Speech-Language Pathologist and Audiologist Reviews

MOTION: Barbara Johnson moved, seconded by Catherine Kanter, to delegate authority to the Department Attorneys to review and approve reciprocity/endorsement applications in which the out-of-state license requirements for a speech-language pathologist or audiologist are substantially equivalent to the Board's requirements. Motion carried unanimously.

Delegated Authority for Application Denial Reviews

MOTION: Kathleen Pazak moved, seconded by Barbara Johnson, to delegate authority to the Department's Attorney Supervisors to serve as the Board's designee for purposes of reviewing and acting on requests for hearing as a result of a denial of a credential. Motion carried unanimously.

Voluntary Surrenders

MOTION: Steven Klapperich moved, seconded by Catherine Kanter, to delegate authority to the assigned case advisor to accept or refuse a request for voluntary surrender pursuant to Wis. Stat. § 440.19 for a credential holder who has a pending complaint or disciplinary matter. Motion carried unanimously.

Continuing Education and Examination Liaison(s) Delegation

MOTION: Catherine Kanter moved, seconded by Steven Klapperich, to delegate authority to the Continuing Education and Examination Liaison(s) to address all issues related to continuing education, and examinations. Motion carried unanimously.

Authorization for DSPS to Provide Board Member Contact Information to National Regulatory Related Bodies

MOTION: Barbara Johnson moved, seconded by Kathleen Pazak, to authorize DSPS staff to provide national regulatory related bodies with all Board member contact information that DSPS retains on file. Motion carried unanimously.

Optional Renewal Notice Insert Delegation

MOTION: Barbara Johnson moved, seconded by Kathleen Pazak to designate the Chairperson (or, in the absence of the Chairperson, the highest-ranking officer or longest serving board member in that succession) to provide a brief statement or link relating to board-related business within the license renewal notice at the Board's or Board designee's request. Motion carried unanimously.

Legislative Liaison(s) Delegation

MOTION: Catherine Kanter moved, seconded by Michael Harris, to delegate authority to the Legislative Liaison(s) to speak on behalf of the Board regarding legislative matters. Motion carried unanimously.

Travel Liaison(s) Delegation

MOTION: Steven Klapperich moved, seconded by Kathleen Pazak, to delegate authority to the Travel Liaison(s) to approve any board member travel. Motion carried unanimously.

Roles and Authorities Delegated for Monitoring

The Monitoring Liaison ("Liaison") is a Board/Section designee who works with department monitors ("Monitor") to enforce Board/Section orders as explained below.

Authorities Delegated to the Monitoring Liaison

The Liaison may take the following actions on behalf of the Board/Section:

1. Grant a temporary reduction in random drug screen frequency upon Respondent's request if he/she is unemployed and is otherwise compliant with Board/Section order. The temporary reduction will be in effect until Respondent secures employment in the profession. The Department Monitor ("Monitor") will draft an order and sign on behalf of the Liaison.

2. Grant a stay of suspension if Respondent is eligible per the Board/Section order. The Monitor will draft an order and sign on behalf of the Liaison.

3. Remove the stay of suspension if there are repeated violations or a substantial violation of the Board/Section order. In conjunction with removal of any stay of suspension, the Liaison may prohibit Respondent from seeking reinstatement of the stay for a specified period of time. The Monitor will draft an order and sign on behalf of the Liaison.

4. Grant or deny approval when Respondent proposes continuing/disciplinary/remedial education courses, treatment providers, mentors, supervisors, change of employment, etc. unless the order specifically requires full-Board/Section approval.

5. Grant a maximum of <u>one 90-day extension</u>, if warranted and requested in writing by Respondent, to complete Board/Section-ordered continuing/disciplinary/remedial education.

6. Grant a maximum of one extension or payment plan for proceeding costs and/or forfeitures if warranted and requested in writing by Respondent.

7. Grant a maximum of one extension, if warranted and requested in writing by Respondent, to complete a Board/Section-ordered evaluation or exam.

8. Grant full reinstatement of licensure if Respondent has fully complied with all terms of the order <u>without deviation</u>. The Monitor will draft an order and obtain written authorization from the Liaison to sign on their behalf.

9. Grant or deny a request to appear before the Board/Section in closed session.

10. The Liaison may determine whether Respondent's petition is eligible for consideration by the full Board/Section.

11. *(Except Pharmacy and Medical)* Accept Respondent's written request to surrender credential. If accepted by the Liaison, Monitor will consult with Board Counsel to determine if a stipulation is necessary. If a stipulation is not necessary, Monitor will draft an order and sign on behalf of the Liaison. If denied by the Liaison, the request to surrender credential will go to the full Board for review.

12. Grant Respondent's petition for a reduction in drug screens per the standard schedule, below. If approved, Monitor will draft an order and sign on behalf of the Liaison. Orders that do not start at 49 screens will still follow the same standard schedule.

    a. Initial: 49 screens (including 1 hair test, if required by original order)
    b. 1st Reduction: 36 screens (plus 1 hair test, if required by original order)
    c. 2nd Reduction: 28 screens plus 1 hair test
    d. 3rd Reduction: 14 screens plus 1 hair test

13. *(Dentistry only)* Ability to approve or deny all requests from a respondent.

14. The Liaison may approve or deny Respondent's request to be excused from drug and alcohol testing for work, travel, etc.

Authorities Delegated to the Department Monitor

The Monitor may take the following actions on behalf of the Board/Section, draft an order and sign:

1) Grant full reinstatement of licensure if education is the sole condition of the limitation and Respondent has submitted the required proof of completion for approved courses.

2) Suspend the license if Respondent has not completed Board/Section-ordered education and/or paid costs and forfeitures within the time specified by the Board/Section order. The Monitor may remove the suspension and issue an order when proof of completion and/or payment have been received.

3) Suspend the license (or remove stay of suspension) if Respondent fails to enroll and participate in an Approved Program for drug and alcohol testing within 30 days of the order, or if Respondent ceases participation in the Approved Program without Board approval. This delegated authority only pertains to respondents who must comply with drug and/or alcohol testing requirements.

4) **Grant or deny approval when Respondent proposes treatment providers [, mentors, supervisors, etc.] unless the Order specifically requires full-Board/Section or Board designee approval.**

Authorities Delegated to Board Legal Counsel

Board Legal Counsel may take the following actions on behalf of the Board/Section:

1. Sign Monitoring orders that result from Board/Section meetings on behalf of the Board/Section Chair.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request:	2) Date when request submitted:
Dana Denny, Administrative Rules Coordinator	December 10, 2021 Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting

3) Name of Board, Committee, Council, Sections:

Hearing and Speech Examining Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
January 10, 2022	☒ Yes ☐ No	Administrative Rule Matters – Discussion and Consideration 1. Review Preliminary Rule Draft - HAS 4 and 6 – Audiometric Testing and Reciprocal Licensure 2. Pending or Possible Rulemaking Projects.

7) Place Item in:	8) Is an appearance before the Board being scheduled? *(If yes, please complete Appearance Request for Non-DSPS Staff)*	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session	☐ Yes ☒ No	

10) Describe the issue and action that should be addressed:

Review and Approve Preliminary Rule Draft for HAS 4 and 6

Review Board's Current Rule Projects

Attachments:

- HAS 4 and 6 Preliminary Rule Draft
- Wisconsin Administrative Code Chapters HAS 4 and 6
- Rule Projects Chart

Copies of current Board Rule Projects Can be Viewed Here: https://dsps.wi.gov/Pages/RulesStatutes/PendingRules.aspx

11) Authorization

Dana Denny — December 10, 2021

Signature of person making this request — **Date**

Supervisor (if required) — **Date**

Executive Director signature (indicates approval to add post agenda deadline item to agenda) — **Date**

Directions for including supporting documents:
1. This form should be attached to any documents submitted to the agenda.
2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.
3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.

STATE OF WISCONSIN
HEARING AND SPEECH EXAMINING BOARD

IN THE MATTER OF RULEMAKING	:	PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE	:	HEARING AND SPEECH
HEARING AND SPEECH	:	EXAMINING BOARD
EXAMINING BOARD	:	ADOPTING RULES
	:	(CLEARINGHOUSE RULE X - XX)

PROPOSED ORDER

An order of the Hearing and Speech Examining Board to **amend** HAS 4.03 (1) and (Note), and 6.04 (6) (b), and to **create** HAS 6.07 (1) (c) and 6.07 (2) (c), relating to reciprocal credentials for service members, former service members and their spouses.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: Sections s. 459.085, 459.26 (2) (am), and 459.28 (2) Stats.

Statutory authority: Sections s. 15.08 (5) (b), 440.09 (5), 459.085, 459.12 (1), 459.26 (2) (am), and 459.28 (2) Stats.

Explanation of agency authority:

Section 15.08 (5) (b), Stats.: "Each examining board "[s]hall promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains, and define and enforce professional conduct and unethical practices not inconsistent with the law relating to the particular trade or profession. . ."

440.09 (5), Stats.: "[t]he department or credentialing board, as appropriate, may promulgate rules necessary to implement this section."

459.085, Stats.: "Audiometric equipment used in the evaluation of hearing sensitivity for the fitting and sale of hearing aids shall be calibrated periodically, as specified by rule by the examining board."

459.12 (1), Stats.: "The examining board may make rules not inconsistent with the laws of this state which are necessary to carry out the intent of this chapter."

459.26 (2) (am), Stats.: "The examining board shall by rule select and approve examinations for audiology."

459.28 (2), Stats.: "The examining board may enter into reciprocal agreements with officials of other states or territories of the United States for licensing speech-language

pathologists and audiologists and grant licenses to applicants who are licensed in those states or territories according to the terms of the reciprocal agreements."

Related statute or rule: None.

Plain language analysis: As reflected in the March 2021 Wisconsin Hearing and Speech Examining Board Biennial report to the Legislature in compliance with s. 227.29 (1), Stats., two rule objectives were listed as items to be addressed as scope projects: (1) updating outdated 1998 ANSI 3.6 audiometric standards; and (2) removing the option of a certificate of clinical competence as an educational licensure requirement.

A third rule objective was to implement 2017 Act 143 which entitles service members, former service members who were discharged within the prior four years under conditions other than dishonorable, and spouses of service members or former service members, to obtain an audiologist or speech language pathology credential if the person resides in Wisconsin, and is in good standing with the governmental authorities in every jurisdiction outside Wisconsin that have granted the individual a credential that qualifies the individual to perform these authorized services under the appropriate credential. The license, once granted, may be renewed indefinitely.

Summary of, and comparison with, existing or proposed federal regulation: None.

Comparison with rules in adjacent states:

Illinois: The Illinois Department of Financial and Professional Regulation (IDFPR) regulates speech-language pathologists and audiologists under the Board of Speech-Language Pathology and Audiology. Certification is provided to individuals who have demonstrated they possess a masters' or doctoral degree from a speech pathology or audiology program and pass the Praxis examination or provide a Certificate of Clinical Competence in Speech-Language Pathology or Audiology awarded by the American Speech-Language-Hearing Association's Clinical Certification Board. (225 ILCS 110/8)

Temporary licenses may be renewed one time only for a 12-month period for individuals serving full-time in the Armed Forces; in an incapacitating illness documented by a currently licensed physician; or any other similar extenuating circumstances. (225 ILCS 1465.41)

In 2019, the Illinois Legislature passed legislation expediting professional licensure for service members and spouses who are active-duty members or whose active-duty service concluded within the preceding 2 years before application. In part, this law states that, once an active member of the military (or their spouse) has submitted all required documents and fee as part of a completed license application, it will be reviewed within 60 days. (20 ILCS 5/5-715)

State of Illinois governance citations regarding audiometric standards, equipment or practices could not be located.

Iowa: The Iowa Department of Public Health (IDPH) regulates speech pathologists and audiologists under the Board of Speech Pathology and Audiology. In Iowa, licensure is provided to those demonstrating proof of either a masters' degree in speech pathology or a doctoral degree in audiology, or the equivalent of one of these degrees and the official completion of at least 400 hours of supervised clinical training, and completion of the Praxis examination (645 IAC 645.303(147))

In Iowa, veterans with an unrestricted professional license in another jurisdiction may apply for licensure by passing any required licensure examination provided credit for examinations previously passed. Licenses are granted if the applicant if the applicant is licensed in the same or similar profession in another jurisdiction whose licensure requirements are substantially equivalent to those required in Iowa, unless the applicant is ineligible for licensure based on other grounds, for example, the applicant's disciplinary or criminal background. If an applicant has not passed the required examination(s) for licensure, the applicant may not be issued a provisional license, but may request that the licensure application be placed in pending status for up to one year or as mutually agreed to provide the applicant with the opportunity to satisfy the examination requirements. (645 IAC—20.3(272C))

State of Iowa governance citations regarding audiometric standards, equipment or practices could not be located.

Michigan: The Michigan Department of Licensing and Regulatory Affairs (MDLRA) regulates speech pathologists and audiologists under the Board of Speech-Language Pathology and the Board of Audiology, respectively. License credentials are provided to individuals who possess a master's degree in speech pathology or a master's degree or doctoral degree in audiology. Those seeking an initial speech pathology license must have performed at least 1,260 hours of postgraduate clinical experience. All those seeking speech-language and audiologist credentials must pass the Praxis examination. (MCL 338.3)

In Michigan, active-duty service members, veterans, spouses, or their qualifying dependents may obtain an initial health profession, occupational license, or certification of registration in a profession or occupation for which they hold a license or registration in another state or country, including waiving the fee for the initial health profession license or registration fee. (MCL 339.411(11)

State of Michigan governance citations regarding audiometric standards, equipment or practices could not be located.

Minnesota: Minnesota speech pathologists and audiologists are regulated by the Minnesota Department of Health, with input from the Speech-Language Pathologist and Audiologist Advisory Council. License credentials are provided to individuals who possess a master's degree in speech pathology or a master's degree or doctoral degree in audiology, including passing the Praxis examination. (2021 MN Statutes, Section 148.515)

In Minnesota, expedited and temporary professional licenses may be provided for those who are currently active-duty members, spouses of those who are active-duty members, or veterans of the military. (MN Statutes, Section 197.4552)

In November 2020, the Minnesota Department of Health Hearing Dispenser Certification Examination adopted ANSI 3.6 guidelines for hearing screening audiometer use and calibration to allow for pure tone audiometry and threshold screening. (MN Hearing Dispenser Certification Examination Standards, 2021)

Summary of factual data and analytical methodologies:

The proposed rules were developed by reviewing the March 2021 Biennial Report to the Legislature in compliance with s. 227.29 (1), Stats. of the Hearing and Speech Examining Board, technical information provided by the American Speech and Hearing Association (ASHA), and 2019 Wisconsin Act 143, which relates to professional reciprocal licensure.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:

The rule will be posted for 14 days on the Department of Safety and Professional Services website to solicit economic impact comments, including how the proposed rules may affect businesses, local municipalities, and private citizens.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis will be attached upon completion.

Effect on small business:

These rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator, Dan Hereth, may be contacted by email at Daniel.Hereth@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Dana Denny, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8366; telephone 608-287-3748; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Dana Denny, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received on or before the public hearing, held on a date to be determined, to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. HAS 4.03 (1) and (Note) are amended to read:

HAS 4.03 (1) Pure tone audiometry must be conducted with a pure tone audiometer which conforms to the American National Standards Institute, Standard ANSI S3.6 ~~1996~~ 2018 approved ~~January 12, 1996~~ September 20, 2018. Such audiometer shall be capable of generating a minimum of 9 discrete frequencies, ranging from 250 Hz through 8 KHz (250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz). Output levels over the frequency range shall conform to standard ANSI S3.6 specified above.

Note: A copy of Standard ANSI S3.6 may be obtained from The American National Standards Institute website at www.ANSI.org, ~~11 West 42nd Street New York, NY 10036~~. Copies of the Standard are on file at the office of the Department of Safety and Professional Services and the Legislative Reference Bureau.

SECTION 2. HAS 6.04 (b) is amended to read:

HAS 6.04 (6) (b) Completed education or training that the board determines is substantially equivalent to passing the Praxis Audiology examination. ~~A certificate of clinical competence in audiology granted by ASHA is considered equivalent.~~

SECTION 3. HAS 6.07 (1) (c) is created to read:

HAS 6.07 (1) (c) A reciprocal speech-language pathology license shall be granted to service members, former service members who were discharged within the prior four years under conditions other than dishonorable, and spouses of service members or former service members to obtain a credential if the person resides in Wisconsin and are in good standing with the governmental authorities in every jurisdiction outside Wisconsin that have granted the dividual a credential that qualifies the individual to perform acts authorized under the appropriate credential granted by the department or credentialing board. The license may be renewed indefinitely.

SECTION 4. HAS 6.07 (2) (c) is created to read:

HAS 6.07 (2) (c) A reciprocal speech-language pathology license shall be granted to servicemembers, former service members who were discharged within the prior four years under conditions other than dishonorable, and spouses of service members or former service members to obtain a credential if the person resides in Wisconsin and are in good standing with the governmental authorities in every jurisdiction outside Wisconsin that have granted the dividual a credential that qualifies the individual to perform acts authorized under the appropriate credential granted by the department or credentialing board. The license may be renewed indefinitely.

SECTION 5. EFFECTIVE DATE. the rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

Chapter HAS 4

HEARING INSTRUMENT SPECIALISTS MEASUREMENT OF HUMAN HEARING

Note: Chapter Had 4 was renumbered Chapter HAS 4 under s. 13.93 (2m) (b) 1, Stats., Register, April, 1992, No. 436.

HAS 4.01 Appropriate procedures for measurement of human hearing. The procedures accepted by the board for the measurement of human hearing by licensees and trainees comprise:

(1) Pure tone audiometry, including air conduction testing and bone conduction testing.

(2) Speech audiometry by live voice, or recorded voice, including speech reception threshold, speech discrimination testing, and most comfortable loudness measurements and loudness discomfort levels.

(3) Appropriate masking when indicated.

(4) Recording and interpretation of audiograms and speech audiometry to determine proper selection and adaptation of hearing instruments.

History: Cr. Register, March, 1975, No. 231, eff. 4–1–75; am. (2) and (4), Register, July, 1992, No. 439, eff. 8–1–92.

HAS 4.02 Ear molds. Taking impressions for ear molds includes:

(1) Otoscopic observation, pre– and post– impression.

(2) Proper cotton or foam block placement.

(3) Impression material insertion.

(4) Removal of completed impression.

(5) Proper ear mold selection.

History: Cr. Register, March, 1975, No. 231, eff. 4–1–75; am. (2), cr. (5), Register, July, 1992, No. 439, eff. 8–1–92; am. (2), Register, July, 1993, No. 451, eff. 8–1–93; am. (1) and (5), Register, July, 1998, No. 511, eff. 8–1–98.

HAS 4.03 Equipment used to measure hearing. **(1)** Pure tone audiometry must be conducted with a pure tone audiometer which conforms to the American National Standards Institute, Standard ANSI S3.6 1996 approved January 12, 1996. Such audiometer shall be capable of generating a minimum of 9 discrete frequencies, ranging from 250 Hz through 8 KHz (250, 500, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz). Output levels over the frequency range shall conform to standard ANSI S3.6 specified above.

Note: A copy of Standard ANSI S3.6 may be obtained by writing to: The American National Standards Institute, 11 West 42nd Street, New York, NY 10036. Copies of the Standard are on file at the office of the Department of Safety and Professional Services and the Legislative Reference Bureau.

(2) A masking source shall be either available within, or capable of being attached to, the audiometer. The masking source shall have one of the following:

(a) White noise capability.

(b) Speech noise capability.

(c) Narrow band noise and white noise or narrow band noise and speech noise capability.

(3) Audiometric equipment used in the evaluation of hearing sensitivity for the fitting and sale of hearing instruments shall be calibrated not less than once every 12 months.

History: Cr. Register, March, 1975, No. 231, eff. 4–1–75; am. Register, July, 1992, No. 439, eff. 8–1–92; am. Register, July, 1993, No. 451, eff. 8–1–93; renum. HAS 4.03 to be 4.03 (1), cr. (2) and (3), Register, July, 1997, No. 499, eff. 8–1–97; am. (1), Register, July, 1998, No. 511, eff. 8–1–98.

HAS 4.04 Appropriate time frame for hearing tests prior to fitting hearing instruments. Appropriate procedures for the measurement of human hearing as described in s. HAS 4.01 shall be performed and documented within 6 months prior to the selling and fitting of a hearing instrument.

History: Cr. Register, June, 1977, No. 258, eff. 7–1–77; corrections made under s. 13.93 (2m) (b) 1., Stats., Register, April, 1992, No. 436; am. Register, July, 1992, No. 439, eff. 8–1–92; am., Register, July, 1998, No. 511, eff. 8–1–98.

Chapter HAS 6

LICENSURE OF SPEECH–LANGUAGE PATHOLOGISTS, AUDIOLOGISTS AND TEMPORARY LICENSEES

Note: Chapter HAS 6 as it existed on May 31, 1993, was repealed and a new chapter HAS 6 was created effective June 1, 1993.

Subchapter I — Speech–Language Pathologists and Audiologists

HAS 6.01 Authority and purpose. The rules in this chapter are adopted by the hearing and speech examining board under the authority of ss. 227.11 (2) and 459.24 to 459.34, Stats., to govern the licensure of speech–language pathologists, audiologists and temporary licensees.

History: Cr. Register, May, 1993, No. 449, eff. 6–1–93; CR 01–043: am. Register October 2001 No. 550, eff. 11–1–01.

HAS 6.02 Definitions. In this chapter and in ch. 459, Stats.:

(1) "ASHA" means the American speech–language hearing association.

(2) "Audiologist" has the meaning given in s. 459.20 (1), Stats.

(3) "Audiology" has the meaning given in s. 459.20 (2), Stats.

(4) "Board" means the hearing and speech examining board.

(4t) "Hearing aid" has the meaning given in s. 459.20 (3g), Stats.

(6) "Postgraduate clinical fellowship" means a program approved by the board consisting of a minimum of 9 months of supervised clinical practice in speech–language pathology provided in the work setting to which an applicant is seeking licensure.

(6a) "Practice of fitting and dealing in hearing aids" has the meaning given in s. 459.20 (3p), Stats.

(7) "Speech–language pathologist" has the meaning given in s. 459.20 (4), Stats.

(8) "Speech–language pathology" has the meaning given in s. 459.20 (5), Stats.

(9) "Supervised clinical practicum" means a program required by a college or university for completion of a master's degree in speech–language pathology or a doctoral degree in audiology.

(10) "Verification of clinical competence" means written confirmation submitted directly to the board by ASHA stating that an applicant holds a certificate of clinical competence in speech–language pathology or audiology.

History: Cr. Register, May, 1993, No. 449, eff. 6–1–93; cr. (4m), Register, August, 1995, No. 476, eff. 9–1–95; cr. (4r), Register, July, 1997, No. 499, eff. 8–1–97; cr. (10), Register, July, 1998, No. 511, eff. 8–1–98; am. (intro.), (2) and (3), cr. (4o), (4t), (6a), (6b) and (8a), Register, February, 1999, No. 518, eff. 3–1–99; CR 01–043: cr. (1m), r. (4o), (4r) and (8a), am. (7) to (9), Register October 2001 No. 550, eff. 11–1–01: CR 03–025: cr. (4g) and (5g) Register January 2004 No. 577, eff. 2–1–04; CR 05–026: am. (1m), r. (4g), (4m), (5g) and (6b) Register September 2005 No. 597, eff. 10–1–05; CR 15–096: r. (1m), (5), am. (6), (9) Register August 2016 No. 728, eff. 9–1–16.

HAS 6.03 Applications for licensure; speech–language pathologist. Every applicant for licensure as a speech–language pathologist shall submit:

(1) An application on a form provided by the board.

Note: Applications are available on the website at dsps.wi.gov or by calling (608) 266 – 2112.

(2) The fee specified in s. 440.05 (1), Stats.

(4) Subject to ss. 111.321, 111.322, and 111.335, Stats., evidence satisfactory to the board that the applicant does not have a conviction record.

(5) Evidence satisfactory to the board that the applicant has satisfied one of the following:

(a) Completed a supervised clinical practicum and received a master's degree in speech–language pathology from a college or university approved by the board.

(b) Completed education or training that the board determines is substantially equivalent to the requirements under par. (a).

(6) Verification the applicant has satisfied one of the following:

(a) Passed the Praxis Speech–Language Pathologist examination.

(b) Completed education or training that the board determines is substantially equivalent to passing the NESPA examination that may include verification that the applicant has been granted a certificate of clinical competence in speech–language pathology by ASHA.

(7) Evidence satisfactory to the board that the applicant has satisfied one of the following:

(a) Completed a postgraduate clinical fellowship in speech–language pathology approved by the board.

(b) Completed education or training that the board determines is substantially equivalent to the completion of a postgraduate clinical fellowship in speech–language pathology.

History: Cr. Register, May, 1993, No. 449, eff. 6–1–93; emerg. am. (6), eff. 12–6–93; am. (6), Register, April, 1994, No. 460, eff. 5–1–94, r. (3), Register, July, 1998, No. 511, eff. 8–1–98; CR 01–043: am. (5), r. and recr. (6), Register October 2001 No. 550, eff. 11–1–01; CR 05–026: renum. (7) to be (7) (intro.), cr. (7) (a) and (b) Register September 2005 No. 597, eff. 10–1–05; CR 15–096: am. (6) (intro.), (a) Register August 2016 No. 728, eff. 9–1–16.

HAS 6.04 Applications for licensure; audiologist. Every applicant for licensure as an audiologist shall submit:

(1) An application on a form provided by the board.

Note: Applications are available on the website at dsps.wi.gov or by calling (608) 266 – 2112.

(2) The fee specified in s. 440.05 (1), Stats.

(4) Subject to ss. 111.321, 111.322 and 111.335, Stats., evidence satisfactory to the board that the applicant does not have a conviction record.

(5) Evidence satisfactory to the board that the applicant has completed a supervised clinical practicum and satisfied one of the following:

(a) Possesses a doctoral degree in audiology from a college or university in an accredited academic program. The doctoral degree program shall consist of not less than 3 years of educational course work and not less than 12 months of clinical rotation or externship.

(b) Evidence satisfactory to the examining board that the applicant has completed education or training that the board determines is substantially equivalent to the requirement under par. (a).

(6) Verification the applicant has satisfied one of the following:

(a) Passed the Praxis Audiology examination.

(b) Completed education or training that the board determines is substantially equivalent to passing the Praxis Audiology examination. A certificate of clinical competence in audiology granted by ASHA is considered equivalent.

(8) Evidence satisfactory to the board that the applicant has passed the practical examination required under s. 459.26 (2) (b), Stats., or has completed education or training that the board determines is substantially equivalent to the completion of the examination.

History: Cr. Register, May, 1993, No. 449, eff. 6–1–93; r. (3), am. (7), Register, July, 1998, No. 511, eff. 8–1–98; cr. (8), Register, February, 1999, No. 518, eff. 3–1–99; CR 01–043: am. (5) and (8), r. and recr. (6) and (7), Register October 2001 No. 550, eff. 11–1–01; CR 15–096: am. (5), (6) (intro.), (a), consol. (6) (b) (intro.) and 1. and renum. (6) (b) and am., r. (6) (b) 2., (7) Register August 2016 No. 728, eff. 9–1–16.

HAS 6.07 Reciprocal license. (1) SPEECH–LANGUAGE PATHOLOGY. The board shall grant a license to practice speech–language pathology to an applicant who pays the fee required by s. 440.05 (2), Stats., and provides evidence of all the following:

(a) The applicant has a current license to practice speech–language pathology in good standing in another state or territory of the United States.

(b) The requirements for licensure in the other state or territory are substantially equivalent to the requirements under s. 459.24 (2), Stats.

(2) AUDIOLOGY. The board shall grant a license to practice audiology to an applicant who pays the fee required by s. 440.05 (2), Stats., and provides evidence of one of the following:

(a) The applicant has a current license to practice audiology in good standing in another state or territory of the United States and the requirements for licensure in the other state or territory are substantially equivalent to the requirements under s. 459.24 (3), Stats.

(b) The applicant has a current license to practice audiology in good standing in another state or territory of the United States and provides evidence of all the following:

1. The requirements for licensure in the other state or territory are substantially equivalent to the requirements under s. 459.24 (3) (c), (e), and (em), Stats.

2. The applicant has completed a supervised clinical practicum and received a master's degree in audiology from a college or university approved by the examining board or has completed education or training that the examining board determines is substantially equivalent to the completion of those requirements.

(3) RECIPROCAL AGREEMENTS. A license to practice speech–language pathology or audiology may be granted to applicants according to the terms of a reciprocal agreement the board has entered into with another state or territory.

History: Cr. Register, May, 1993, No. 449, eff. 6–1–93; CR 01–043: am. (1) (intro) and (c), Register October 2001 No. 550, eff. 11–1–01; CR 15–096: r. and recr. Register August 2016 No. 728, eff. 9–1–16; correction in (1) (intro.), (2) (intro.) made under s. 35.17, Stats., Register August 2016 No. 728, eff. 9–1–16.

HAS 6.08 Limited permit. (1) A non–resident applicant for a limited permit to practice in association with a licensed speech–language pathologist or licensed audiologist for a period not to exceed 10 days in any calendar year shall submit the application, pay the fee specified in s. 440.05 (6), Stats., and provide evidence of all of the following:

(a) The applicant does not have an arrest or conviction record, subject to ss. 111.321, 111.322, and 111.335, Stats.

(b) Completion of one of the following:

1. The requirements in s. HAS 6.03 (5) for the practice of speech–language pathology.

2. The requirements in s. HAS 6.04 (5) for the practice of audiology.

(2) A non–resident applicant for a limited permit to practice speech–language pathology or audiology, who holds a current speech–language pathologist or audiologist license in another state or territory of the United States which has requirements determined by the board to be substantially equivalent to the requirements under s. 459.24 (2) or (3), Stats., shall submit the application, pay the fee specified in s.440.05 (6), Stats., and provide evidence the applicant holds a current license in good standing. The limited permit shall be valid for a period not to exceed 45 days in any calendar year.

History: Cr. Register, May, 1993, No. 449, eff. 6–1–93; am. (1) (b) and (2) (b), Register, January, 1994, No. 457, eff. 2–1–94; r. (1) (c), cr. (1) (d) and (e), am. (2) (b) and (3), Register, July, 1998, No. 511, eff. 8–1–98; am. (2) (b), Register, February, 1999, No. 518, eff.3–1–99; CR 01–043: r. and recr. (1) (e) 2., am. (2) (b), (c) and (3), Register October 2001 No. 550, eff. 11–1–01; CR 15–096: r. and recr. Register August 2016 No. 728, eff. 9–1–16; correction in (1) (intro.), (2) made under s. 35.17, Stats., Register August 2016 No. 728.

HAS 6.085 Accommodations relating to a disability. A qualified applicant with a disability shall be provided with reasonable accommodations requested in connection with the completion of an application for a credential.

History: Cr. Register, July, 1998, No. 511, eff. 8–1–98.

Subchapter II — Temporary Licensees

HAS 6.09 Definitions. In this subchapter and in ch. 459, Stats.:

(1) "Hardship" means serious illness or some other personal adversity, as determined by the board.

(1m) "Sufficient cause" means illness or other hardship.

(2) "Supervision" means any of the following:

(a) A face–to–face meeting, at least monthly, between the supervisor and the temporary licensee and other on–going communications by mail, telephone, pager, e–mail or other electronic means.

(b) On–site, in–view observation and guidance by the supervisor while an assigned activity is performed by the temporary licensee.

History: CR 01–043: Cr. Register October 2001 No. 550, eff. 11–1–01; CR 05–026: renum. (1) to be (1m), cr. (1) Register September 2005 No. 597, eff. 10–1–05; CR 15–096: r. (3) Register August 2016 No. 728, eff. 9–1–16.

HAS 6.10 Temporary licenses. (1) SPEECH–LANGUAGE PATHOLOGY. (a) Before commencing a postgraduate clinical fellowship in speech–language pathology an applicant shall obtain a temporary license to practice under the supervision of a licensed speech–language pathologist by submitting all the following:

1. An application and fee specified in s. 440.05 (6), Stats.

2. Evidence the applicant does not have an arrest or conviction record, subject to ss. 111.321, 111.322, and 111.335, Stats.

3. Evidence the applicant has completed one of the following:

a. A supervised clinical practicum and received a master's degree in speech–language pathology from a college or university approved by the board.

b. Education or training that the board determines is substantially equivalent to the completion of the supervised clinical practicum and master's degree in speech–language pathology.

4. Evidence of the applicant is registered to take the next available Praxis Speech–Language Pathology examination or has passed the Praxis Speech–Language Pathology examination or has completed education or training that the board determines is substantially equivalent to passing the examination.

(b) A temporary license to practice speech–language pathology is valid for 18 months. A temporary license may be renewed once by the board.

(c) Notwithstanding par. (b), a temporary license to practice speech–language pathology shall terminate in 90 days if an applicant fails to take the next available examination for reasons other than inaction by the examining board or hardship.

(d) A person holding a temporary license to practice speech–language pathology shall be supervised face–to–face, at least monthly, by a licensed speech–language pathologist. The person holding the temporary license shall have the supervisor, once a month, provide written approval in the client files of the clinical services provided.

(2) AUDIOLOGY. (a) A temporary license to practice audiologist may be granted by submitting of all of the following:

1. An application and fee specified in s. 440.05 (6), Stats.

2. Evidence the applicant does not have an arrest or conviction record, subject to ss. 111.321, 111.322, and 111.335, Stats.

3. Evidence the applicant has completed a supervised clinical practicum and one of the following:

a. Possesses a doctoral degree in audiology from an accredited academic institution approved by the board. The doctoral degree program shall consist of not less than 3 years of educational course work and not less than 12 months of clinical rotation or externship.

b. Education or training that the board determines is substantially equivalent to the completion of the requirement under subd. 3. a.

4. Evidence the applicant has passed the Praxis Audiologist examination.

(b) A temporary license to practice audiology is valid for 6 months. A temporary license may be renewed once by the board, for a time period to allow the applicant time to take the next available examination and receive the results of the examination, if one of the following occurs:

1. The applicant fails the practical exam required under s. 459.26 (2) (b), Stats., and applies to take the next available examination.

2. The applicant shows to the satisfaction of the examining board sufficient cause for the renewal.

History: CR 01–043: cr. Register October 2001 No. 550, eff. 11–1–01; CR 05–026: am. (1) (intro.) and (2), renum. (3) to be (6), cr. (3) to (5) Register September 2005 No. 597, eff. 10–1–05; CR 15–096: r. and recr. Register August 2016 No. 728, eff. 9–1–16.

HAS 6.12 Use of titles. An individual who holds a temporary license under s. 459.24 (6), Stats., may use the title "audiology intern," "speech–language pathology intern," "clinical fellow in audiology," or "clinical fellow in speech–language pathology."

History: CR 01–043: cr. Register October 2001 No. 550, eff. 11–1–01.

HAS 6.13 Discipline. Temporary licensees and speech–language pathologists and audiologists who supervise temporary licensees may be subject to discipline under s. HAS 6.18.

History: CR 01–043: cr. Register October 2001 No. 550, eff. 11–1–01.

Subchapter III — Unlicensed Individuals

HAS 6.14 Definitions. In this chapter and in ch. 459, Stats.:

(1) (a) "Assist in the practice of speech–language pathology" means providing speech–language pathology services, while under direct supervision, that include any of the following:

1. Assisting the speech–language pathologists with speech–language screenings.

2. While in the presence of the speech–language pathologist, providing assistance during client evaluations.

3. Helping with informal documentation such as taking a written language sample; organizing test materials; preparing treatment materials; developing communication boards and performing assigned clerical duties.

4. Scheduling activities, preparing charts, records, graphs or displaying data related to client performance.

5. Performing calibration and regular maintenance of equipment.

6. Participating in research projects, in–service training and public relations programs.

7. While in the presence of the speech–language pathologist, providing assistance during a treatment session conducted by the speech–language pathologist that may include any of the following:

a. Structured speech–language drills; oral motor exercises; practice and reinforcement of established speech–language skills and applications to communication activities of daily living.

b. Informal documentation of the client's response to treatment.

8. Providing treatment to clients selected by the speech–language pathologist by adhering to the treatment plans established by the speech–language pathologist who is available on site for consultation, as needed.

(b) "Assist in the practice of speech–language pathology" does not include any of the following:

1. Performing formal or informal speech–language pathology evaluations.

2. Interpreting screening or test results.

3. Participating in client conferences or interdisciplinary team meetings or communicating with a client's family or other individuals outside of the presence of the supervising speech–language pathologist unless authorized by the speech–language pathologist.

4. Writing evaluation consultation reports.

5. Counseling or consulting with the client, the client's family or other individuals regarding the client's status or service.

6. Writing, developing or modifying a client's individualized treatment plan.

7. Deviating from the treatment plan.

8. Working with clients without direct supervision by the speech–language pathologist.

9. Signing formal client documents such as evaluations or progress notes.

10. Selecting clients for service or discharging clients from service.

11. Disclosing confidential client information to anyone other than the supervising speech–language pathologist unless authorized by the supervising speech–language pathologist.

12. Referring a client to another health care provider.

13. Representing himself or herself as a speech–language pathologist.

14. Using a checklist to tabulate results of feeding or swallowing evaluations.

15. Demonstrating swallowing strategies or precautions to a client, the family of a client or staff.

(2) (a) "Assist in the practice of audiology" means providing audiology services that include any of the following:

1. Conducting hearing screenings including pure tone thresholds.

2. Servicing hearing instruments including applying lubrication, making tube changes on ear molds, cleaning and repairing cases or ear mold surfaces, checking battery status and returning hearing instruments to clients after servicing.

3. Preparing informal documentation of clients' responses to treatment or service.

4. Performing biological checks, calibrations and regular maintenance of equipment.

5. Preparing charts and records, scheduling activities and performing assigned clerical duties.

(b) "Assist in the practice of audiology" does not mean any of the following:

1. Performing diagnostic audiological evaluations.

2. Interpreting screening or test results.

3. Writing evaluation consultation reports.

4. Providing counseling to the client or the client's family.

5. Signing formal client documents including evaluations and progress notes.

6. Disclosing confidential client information unless authorized by the supervising audiologist.

7. Referring a client to another health care provider.

(3) "Direct supervision of unlicensed individuals" means:

(a) For purposes of monitoring unlicensed individuals who assist in the practice of speech–language pathology, providing direct observation and supervision of the clinical services provided by the individual to clients at least 50% of client contact time during the first 90 days of employment and no less than 10% thereafter. Direct supervision shall be scheduled and documented. Documentation of direct supervision shall include all of the following:

1. Identifying specific roles and tasks for the individual.

2. Ensuring that the tasks performed by the individual do not require the exercise of professional judgment or entail interpretation of results or the development or modification of treatment plans.

3. Providing appropriate training that is competency–based and specific to job performance.

4. Maintaining a record of direct supervision provided by the speech–language pathologist over the unlicensed individual who assists in the practice of speech–language pathology.

(b) For purposes of monitoring unlicensed individuals who assist in the practice of audiology, providing comprehensive, periodic and documented supervision that includes:

1. Identifying specific roles and tasks for the individual.

2. Ensuring that the tasks performed by the individual do not require the exercise of professional judgment or entail interpretation of results or the development or modification of treatment plans.

3. Providing appropriate training that is competency–based and specific to job performance.

(4) "Full–time equivalent individual" means an unlicensed individual who, alone or in conjunction with other unlicensed individuals, assists in the practice of speech–language pathology or audiology for a combined total of 40 hours per week.

History: CR 01–043: cr. Register October 2001 No. 550, eff. 11–1–01; CR 03–025: am. (1) (a) 1. and 2., (b) 5. and 7., (2) (a) 2., (3) (a) (intro.), and 4., renum. (1) (a) 2. a. to d. and 3. (intro.) to be (1) (a) 3., 4., 5., 6. and 7., renum. and am. (1) (a) 4. to be (1) (a) 8., cr. (1) (b) 13., 14. and 15. Register January 2004 No. 577, eff. 2–1–04.

HAS 6.15 Direct supervision. (1) An unlicensed individual may assist in the practice of speech–language pathology or audiology only under the direct supervision of a speech–language pathologist or audiologist, as appropriate.

(2) For purposes of supervising unlicensed individuals who assist in the practice of speech–language pathology or audiology:

(a) A speech–language pathologist may supervise up to 2 full–time equivalent individuals at any given time.

(b) Except as provided in par. (c), an audiologist may supervise up to 5 full–time equivalent individuals at any given time.

(c) In industrial settings, an audiologist may supervise up to 10 full–time equivalent individuals at any given time.

History: CR 01–043: cr. Register October 2001 No. 550, eff. 11–1–01.

HAS 6.16 Prohibited practice and use of titles. No person may engage in the practice of speech–language pathology or use the title "speech–language pathologist" or any similar title or engage in the practice of audiology or use the title "audiologist", "clinical audiologist" or any similar title, unless the person holds a current speech–language pathologist or audiologist license, as appropriate, granted by the board.

History: CR 01–043: cr. Register October 2001 No. 550, eff. 11–1–01.

HAS 6.17 Discipline. A speech–language pathologist or audiologist who supervises an unlicensed individual may be subject to discipline under s. HAS 6.18.

History: CR 01–043: cr. Register October 2001 No. 550, eff. 11–1–01.

Subchapter IV — Discipline

HAS 6.175 Definitions. In this subchapter and in subchapter II of ch. 459, Stats.:

(1) "Cerumen management" means the removal of cerumen from the external auditory canal by the utilization of methods and techniques performed in accordance with minimum standards and procedures established in the audiological profession.

(1m) "Deceptive advertising" means creating, using, or promoting the use of any advertising material, promotional literature, testimonial, guarantee, warranty, label, brand, insignia, or other representation, however disseminated or published, which is misleading, false, or untruthful.

(2) "Full terms of sale" means the conditions of a sale agreed to by an audiologist and the purchaser of a hearing instrument.

(3) "Personal guarantee" means a promise made by an audiologist to a hearing instrument purchaser to provide the minimum product warranty offered by a manufacturer.

(4) "Sell" or "sale" has the meaning given in s. 459.20 (3t), Stats.

(5) "Unprofessional conduct" means the violation of any standard of professional behavior, which through experience, state statute or administrative rule has become established in the practice of speech–language pathology or audiology.

History: CR 05–026: cr. Register September 2005 No. 597, eff. 10–1–05; CR 12–050: cr. (1m) Register August 2013 No. 692, eff. 9–1–13.

HAS 6.18 Grounds for discipline. (1) The board may reprimand a speech–language pathologist, audiologist, temporary licensee or a permittee, or deny, limit, suspend or revoke a license or permit, if it finds that the applicant, licensee or permittee has done any of the following:

(a) Made a material misstatement in an application for a license or permit or for renewal of a license.

(b) Engaged in conduct in the practice of speech–language pathology or audiology which evidences a lack of knowledge or ability to apply professional principles or skills.

(c) Subject to ss. 111.321, 111.322 and 111.335, Stats., been convicted of an offense the circumstances of which substantially relate to the practice of speech–language pathology or audiology.

(d) Engaged in deceptive advertising.

(e) Advertised, practiced, or attempted to practice under another individual's name.

(f) Subject to ss. 111.321, 111.322 and 111.34, Stats., practiced speech–language pathology or audiology while the person's ability to practice was impaired by alcohol or other drugs.

(g) Violated ch. 459, Stats., subchapter II, or any rule promulgated by the board under that subchapter.

(h) Engaged in unprofessional conduct.

(2) In this subchapter and in s. 459.34 (2) (h), Stats., the following, without limitation because of enumeration, are violations of standards of professional behavior that constitute unprofessional conduct:

(a) Subject to ss. 111.321, 111.322 and 111.34, Stats., practicing or attempting to practice speech–language pathology or audiology while the person's ability to practice is impaired by a mental or emotional disorder.

(b) Using the title "speech–language pathologist," "audiologist" or any similar title unless the individual holds a current speech–language pathologist or audiologist license granted under s. 459.24 (2) or (3), Stats.

(c) Violating the conditions or limitations placed upon a license or permit by the board.

(d) Engaging in conduct likely to deceive, defraud, or harm an individual or the public in the course of the practice of speech–language pathology or audiology.

(e) Having a license, certificate, permit or registration issued by another jurisdiction to practice as a speech–language pathologist or audiologist limited, suspended or revoked.

(f) Aiding or abetting an unlicensed person, knowingly conspiring with an unlicensed person, or allowing one's license to be used by an unlicensed person to evade the use of a title prohibited under s. 459.24 (1) or (1m), Stats.

(g) Engaging in sexual intimacies in connection with the practice of speech–language pathology or audiology.

(h) Failing to fully inform persons served of the nature and possible adverse effects of services rendered and products dispensed.

(i) Failing to evaluate the effectiveness of services rendered or products dispensed.

(j) Providing services or dispensing products when benefits cannot reasonably be expected.

(k) Guaranteeing the results of any treatment or procedure, directly or by implication, except that a reasonable statement of prognosis may be made.

(L) Evaluating or treating speech, language, or hearing disorders except in a professional relationship.

(m) Treating solely by correspondence.

(n) Failing to maintain adequate records of professional services rendered and products dispensed for a period of 5 years.

Note: Speech–language pathologists and audiologists are also required to maintain patient health care records in accordance with ss. 146.81 to 146.84, Stats.

(o) Failing to provide access to records of professional services rendered and products dispensed when requested by the board or its representative in connection with an investigation of a complaint filed against the applicant, licensee or permittee.

(p) Failing to record all of the following information in each client record:

1. The name of the licensee.
2. The date of entry of pertinent information.
3. Information sufficiently legible to allow interpretation by other individuals for the benefit of the client.

(q) Misrepresenting diagnostic information, services rendered, or products dispensed or engaging in any scheme to defraud in connection with obtaining reimbursement.

(r) Using persons in research or as the subject of a teaching demonstration without obtaining their informed consent.

(s) Failing to practice speech–language pathology or audiology within the scope of the licensee's competence, education, training and experience.

(t) Delegating the provision of clinical services to an unlicensed individual for whom the licensee does not provide direct supervision.

(u) Delegating the provision of clinical services to a temporary licensee for whom the licensee does not provide supervision.

(v) Knowingly permitting any professional staff or unlicensed individual to provide clinical services that exceed that person's competence, education, training and experience.

(w) Failing to assign credit to persons who have contributed to clinical services, a publication, presentation or product in proportion to their contribution.

(x) Violating any federal or state statute, rule or regulation that relates to the practice of speech–language pathology or audiology, as appropriate.

(3) In addition to the bases for unprofessional conduct set forth under sub. (2), the board may reprimand an audiologist, or deny, limit, suspend or revoke a license or permit, if it finds that the applicant, licensee or permittee has engaged in the following unprofessional conduct:

(a) Violated any federal or state statute, rule or regulation that relates to the practice of fitting and dealing in hearing aids.

(b) Failed to conduct a direct observation of the ear canal of a person for whom a hearing aid is purchased.

(c) Sold a hearing aid for use by a person who was not given tests by a hearing instrument specialist or an audiologist licensed under ch. 459, Stats., or in another state using appropriate procedures and instrumentation or without proper measurement of the functional intensity and range of the person's hearing.

(d) Failed to calibrate audiometric equipment at least once every 12 months.

(e) Failed to maintain adequate records of certification of calibrations of audiometric equipment for a period of 5 years or failed to provide access to those records when requested by the board or its representative.

(f) Failed to clearly state the full terms of sale on a receipt, as required in s. 459.24 (3m), Stats., or failed to comply with those terms. The full terms of sale shall include all of the following:

1. The amount and method of payment.
2. The date and place of delivery.
3. The terms of any personal guarantee.
4. The nature and duration of the trial period and extension, if any.
5. The refund policy and amount, if any.
6. The product return and exchange policy, if any.
7. The product repair policy, if any.

(g) Failed to perform cerumen management in a competent manner.

History: CR 01–043: cr. Register October 2001 No. 550, eff. 11–1–01; CR 03–025: cr. (1) (h), (2) (d), (e) and (f) Register January 2004 No. 577, eff. 2–1–04; CR 05–026: renum. (2) and (3) to be (3) and (2) and am. Register September 2005 No. 597, eff. 10–1–05; CR 112–050: am. (1) (d) Register August 2013 No. 692, eff. 9–1–13.

Hearing and Speech Examining Board
Rule Projects (updated 12/10/21)

Clearinghouse Rule Number	Scope #	Scope Expiration	Code Chapter Affected	Relating clause	Current Stage	Next Step
21-025	109-20	02/17/2023	HAS 1 and 2	Direct Supervision of Hearing Instrument Specialist Temporary Trainees	Ready for Adoption Order	Adoption Order to be presented at April 2022 Meeting
Not Assigned Yet	079-21	03/31/2024	HAS 4 and 6	Audiometric Testing and Reciprocal Licensure	Drafting	Posting for EIA Comment and Submission to Clearinghouse
Not Assigned Yet	108-20	02/17/2023	HAS 5 and 6	Telehealth	Paused Pending Results of SB 309 (AB 296)	Depends on What Route the Board Would Like to Take after Receiving Results of SB 309

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request:		2) Date When Request Submitted: 12/15/2021 Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting	
3) Name of Board, Committee, Council, Sections: Hearing and Speech Examining Board			
4) Meeting Date: 1/10/2022	5) Attachments: ☐ Yes ☒ No	6) How should the item be titled on the agenda page? FDA Proposed Guidelines on Over the Counter Hearing Aids – Board Discussion	
7) Place Item in: ☒ Open Session ☐ Closed Session	8) Is an appearance before the Board being scheduled? ☐ Yes (Fill out Board Appearance Request) ☒ No	9) Name of Case Advisor(s), if required:	

10) Describe the issue and action that should be addressed:

Executive Order on Promoting Competition in the American Economy:

https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/09/fact-sheet-executive-order-on-promoting-competition-in-the-american-economy/

Federal Register: Establishing Over-the -Counter Hearing Aids:

https://www.federalregister.gov/documents/2021/10/20/2021-22473/medical-devices-ear-nose-and-throat-devices-establishing-over-the-counter-hearing-aids

Supervisor (if required) Date

Executive Director signature (indicates approval to add post agenda deadline item to agenda) Date

Directions for including supporting documents:
1. This form should be attached to any documents submitted to the agenda.
2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.
3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.

BRIEFING ROOM

FACT SHEET: Executive Order on Promoting Competition in the American Economy

JULY 09, 2021 • STATEMENTS AND RELEASES

The economy is booming under President Biden's leadership. The economy has gained more than three million jobs since the President took office—the most jobs created in the first five months of any presidency in modern history. Today, the President is building on this economic momentum by signing an Executive Order to promote competition in the American economy, which will lower prices for families, increase wages for workers, and promote innovation and even faster economic growth.

For decades, corporate consolidation has been accelerating. In over 75% of U.S. industries, a smaller number of large companies now control more of the business than they did twenty years ago. This is true across healthcare, financial services, agriculture and more.

That lack of competition drives up prices for consumers. As fewer large players have controlled more of the market, mark-ups (charges over cost) have tripled. Families are paying higher prices for necessities—things like prescription drugs, hearing aids, and internet service.

Barriers to competition are also driving down wages for workers. When there are only a few employers in town, workers have less opportunity to bargain for a higher wage and to demand dignity and respect in the workplace. In fact, research shows that industry consolidation is decreasing advertised wages by as much as 17%. Tens of millions of Americans—including those working in construction and retail—are required to sign non-compete agreements as a condition of getting a job, which makes it harder for them to switch to better-paying options.

In total, higher prices and lower wages caused by lack of competition are now estimated to cost the median American household $5,000 per year.

Inadequate competition holds back economic growth and innovation. The rate of new business formation has fallen by almost 50% since the 1970s as large businesses make it harder for Americans with good ideas to break into markets. There are fewer opportunities for existing

small and independent businesses to access markets and earn a fair return. Economists find that as competition declines, productivity growth slows, business investment and innovation decline, and income, wealth, and racial inequality widen.

When past presidents faced similar threats from growing corporate power, they took bold action. In the early 1900s, Teddy Roosevelt's Administration broke up the trusts controlling the economy—Standard Oil, J.P. Morgan's railroads, and others—giving the little guy a fighting chance. In the late 1930s, FDR's Administration supercharged antitrust enforcement, increasing more than eightfold the number of cases brought in just two years—enforcement actions that saved consumers billions in today's dollars and helped unleash decades of sustained, inclusive economic growth.

Today President Biden is taking decisive action to reduce the trend of corporate consolidation, increase competition, and deliver concrete benefits to America's consumers, workers, farmers, and small businesses. **Today's historic Executive Order established a whole-of-government effort to promote competition in the American economy.** The Order **includes 72 initiatives by more than a dozen federal agencies to promptly tackle some of the most pressing competition problems across our economy.** Once implemented, these initiatives will result in concrete improvements to people's lives.

Among other things, they will:

- Make it easier to change jobs and help raise wages by banning or limiting non-compete agreements and unnecessary, cumbersome occupational licensing requirements that impede economic mobility.
- Lower prescription drug prices by supporting state and tribal programs that will import safe and cheaper drugs from Canada.
- Save Americans with hearing loss thousands of dollars by allowing hearing aids to be sold over the counter at drug stores.
- Save Americans money on their internet bills by banning excessive early termination fees, requiring clear disclosure of plan costs to facilitate comparison shopping, and ending landlord exclusivity arrangements that stick tenants with only a single internet option.
- Make it easier for people to get refunds from airlines and to comparison shop for flights by requiring clear upfront disclosure of add-on fees.
- Make it easier and cheaper to repair items you own by limiting manufacturers from barring self-repairs or third-party repairs of their products.

- Make it easier and cheaper to switch banks by requiring banks to allow customers to take their financial transaction data with them to a competitor.

- Empower family farmers and increase their incomes by strengthening the Department of Agriculture's tools to stop the abusive practices of some meat processors.

- Increase opportunities for small businesses by directing all federal agencies to promote greater competition through their procurement and spending decisions.

The Order also encourages the leading antitrust agencies to focus enforcement efforts on problems in key markets and coordinates other agencies' ongoing response to corporate consolidation. The Order:

- Calls on the leading antitrust agencies, the Department of Justice (DOJ) and Federal Trade Commission (FTC), to **enforce the antitrust laws vigorously** and recognizes that the law allows them to **challenge prior bad mergers** that past Administrations did not previously challenge.

- Announces a policy that enforcement should focus in particular on **labor markets, agricultural markets, healthcare markets (which includes prescription drugs, hospital consolidation, and insurance)**, **and the tech sector.**

- Establishes a **White House Competition Council, led by the Director of the National Economic Council,** to monitor progress on finalizing the initiatives in the Order and to coordinate the federal government's response to the rising power of large corporations in the economy.

A more detailed summary of the key actions in the Order is provided below:

Labor Markets

Competition in labor markets can empower workers to demand higher wages and greater dignity and respect in the workplace. One way companies stifle competition is with non-compete clauses. Roughly half of private-sector businesses require at least some employees to enter non-compete agreements, affecting some 36 to 60 million workers.

Overly burdensome occupational licensing requirements also restrict competition. In certain occupations, such as skilled construction trades, licensing is critical to protecting public health and safety and increasing wages for workers who acquire in-demand skills and knowledge. In other occupations, however, it can impede worker mobility without countervailing benefits. Today, almost 30% of jobs in the United States require a license, up from less than

5% in the 1950s. Fewer than 5% of occupations that require licensing in at least one state are treated consistently across all 50 states. That locks some people out of jobs, and it makes it harder for people to move between states—particularly burdening military spouses, 34% of whom work in a field requiring a license and are subject to military-directed moves every few years.

Workers may also be harmed by existing guidance provided by the Department of Justice and Federal Trade Commission to Human Resource personnel that allows third parties to make wage data available to employers—and not to workers—in certain circumstances without triggering antitrust scrutiny. This may be used to collaborate to suppress wages and benefits.

In the Order, the President:

- Encourages the FTC to **ban or limit non-compete agreements**.
- Encourages the FTC to **ban unnecessary occupational licensing restrictions that impede economic mobility**.
- Encourages the FTC and DOJ to strengthen antitrust guidance to **prevent employers from collaborating to suppress wages or reduce benefits** by sharing wage and benefit information with one another.

These actions complement the President's call for Congress to pass the Protecting the Right to Organize (PRO) Act to ensure workers have a free and fair choice to join a union and to collectively bargain. Unions are critical to empowering workers to bargain with their employers for better jobs and to creating an economy that works for everyone.

Healthcare

The proposed Order tackles four areas where lack of competition in healthcare increases prices and reduces access to quality care.

Prescription Drugs: Americans pay more than 2.5 times as much for the same prescription drugs as peer countries, and sometimes much more. Price increases continue to far surpass inflation. As a result, nearly one in four Americans report difficulties paying for medication, and nearly one in three Americans report not taking their medications as prescribed.

These high prices are in part the result of lack of competition among drug manufacturers. The largest pharmaceutical companies are able to wield their market power to reap average annual

profits of 15-20%, as compared to average annual profits of 4-9% for the largest non-drug companies.

One strategy that drug manufacturers have used to avoid competing is "pay for delay" agreements, in which brand-name drug manufacturers pay generic manufacturers to stay out of the market. That has raised drug prices by $3.5 billion per year, and research also shows that "pay for delay" and similar deals between generic and brand name manufacturers reduce innovation—reducing new drug trials and R&D expenditures.

In the Order, the President:

- Directs the Food and Drug Administration to **work with states and tribes to safely import prescription drugs from Canada**, pursuant to the Medicare Modernization Act of 2003.
- Directs the Health and Human Services Administration (HHS) to increase **support for generic and biosimilar drugs**, which provide low-cost options for patients.
- Directs HHS to issue **a comprehensive plan within 45 days to combat high prescription drug prices and price gouging**.
- Encourages the FTC to **ban "pay for delay" and similar agreements by rule.**

Hearing Aids: Hearing aids are so expensive that only 14% of the approximately 48 million Americans with hearing loss use them. On average, they cost more than $5,000 per pair, and those costs are often not covered by health insurance. A major driver of the expense is that consumers must get them from a doctor or a specialist, even though experts agree that medical evaluation is not necessary. Rather, this requirement serves only as red tape and a barrier to more companies selling hearing aids. The four largest hearing aid manufacturers now control 84% of the market.
In 2017, Congress passed a bipartisan proposal to allow hearing aids to be sold over the counter. However, the Trump Administration Food and Drug Administration failed to issue the necessary rules that would actually allow hearing aids to be sold over the counter, leaving millions of Americans without low-cost options.

In the Order, the President:

- Directs HHS to consider issuing **proposed rules within 120 days for allowing hearing aids to be sold over the counter.**

Hospitals: Hospital consolidation has left many areas, especially rural communities, without good options for convenient and affordable healthcare service. Thanks to unchecked mergers, the ten largest healthcare systems now control a quarter of the market. Since 2010, 138 rural hospitals have shuttered, including a high of 19 last year, in the middle of a healthcare crisis. Research shows that hospitals in consolidated markets charge far higher prices than hospitals in markets with several competitors.

In the Order, the President:

- **Underscores that hospital mergers can be harmful** to patients and encourages the Justice Department and FTC to review and revise their merger guidelines to ensure patients are not harmed by such mergers.
- Directs HHS to **support existing hospital price transparency rules and to finish implementing bipartisan federal legislation to address surprise hospital billing**.

Health Insurance: Consolidation in the health insurance industry has meant that many consumers have little choice when it comes to selecting insurers. And even when there is some choice, comparison shopping is hard because plans offered on the exchanges are complicated—with different services covered or different deductibles.

In the Order, the President:

- Directs HHS to **standardize plan options in the National Health Insurance Marketplace so people can comparison shop** more easily.

Transportation

In the transportation sector, multiple industries are now dominated by large corporations—air travel, rail, and shipping.

Airlines: The top four commercial airlines control nearly two-thirds of the domestic market. Reduced competition contributes to increasing fees like baggage and cancellation fees. These fees are often raised in lockstep, demonstrating a lack of meaningful competitive pressure, and are often hidden from consumers at the point of purchase. The top ten airlines collected $35.2 billion in ancillary fees in 2018, up from just $1.2 billion in 2007. Inadequate competition also reduces incentives to provide good service. For example, the Department of Transportation (DOT) estimates that airlines were late delivering at least 2.3 million checked bags in 2019.

In the Order, the President:

- Directs the DOT to consider issuing **clear rules requiring the refund of fees when baggage is delayed or when service isn't actually provided**—like when the plane's WiFi or in-flight entertainment system is broken.
- Directs the DOT to consider issuing **rules that require baggage, change, and cancellation fees to be clearly disclosed** to the customer.

Rail: In 1980, there were 33 "Class I" freight railroads, compared to just seven today, and four major rail companies now dominate their respective geographic regions. Freight railroads that own the tracks can privilege their own freight traffic—making it harder for passenger trains to have on-time service—and can overcharge other companies' freight cars.

In the Order, the President:

- Encourages the Surface Transportation Board to **require railroad track owners to provide rights of way to passenger rail** and to strengthen their obligations to **treat other freight companies fairly**.

Shipping: In maritime shipping, the global marketplace has rapidly consolidated. In 2000, the largest 10 shipping companies controlled 12% of the market. Today, it is more than 80%, leaving domestic manufacturers who need to export goods at these large foreign companies' mercy. This has let powerful container shippers charge exporters exorbitant fees for time their freight was sitting waiting to be loaded or unloaded. These fees, called "detention and demurrage charges," can add up to hundreds of thousands of dollars.

In the Order, the President:

- Encourages the Federal Maritime Commission to **ensure vigorous enforcement against shippers charging American exporters exorbitant charges**.

Agriculture

Over the past few decades, key agricultural markets have become more concentrated and less competitive. The markets for seeds, equipment, feed, and fertilizer are now dominated by just a few large companies, meaning family farmers and ranchers now have to pay more for these inputs. For example, just four companies control most of the world's seeds, and corn seed prices have gone up as much as 30% annually.

Consolidation also limits farmers' and ranchers' options for selling their products. That means they get less when they sell their produce and meat—even as prices rise at the grocery store. For example, four large meat-packing companies dominate over 80% of the beef market and, over the last five years, farmers' share of the price of beef has dropped by more than a quarter—from 51.5% to 37.3%—while the price of beef has risen.

Overall, farmers' and ranchers' share of each dollar spent on food has been declining for decades. In short, family farmers and ranchers are getting less, consumers are paying more, and the big conglomerates in the middle are taking the difference.

Meanwhile, the law designed to combat these abuses—the Packers and Stockyards Act—was systematically weakened by the Trump Administration Department of Agriculture (USDA).

American farmers and ranchers are also getting squeezed by foreign corporations importing meat from overseas with labels that mislead customers about its origin. Under current labeling rules, meat can be labeled "Product of USA" if it is only processed here—including when meat is raised overseas and then merely processed into cuts of meat here. For example, most grass-fed beef labeled "Product of USA" is actually imported. That makes it hard or impossible for consumers to know where their food comes from and to choose to support American farmers and ranchers.

Corporate consolidation even affects farmers' ability to repair their own equipment or to use independent repair shops. Powerful equipment manufacturers—such as tractor manufacturers—use proprietary repair tools, software, and diagnostics to prevent third-parties from performing repairs. For example, when certain tractors detect a failure, they cease to operate until a dealer unlocks them. That forcers farmers to pay dealer rates for repairs that they could have made themselves, or that an independent repair shop could have done more cheaply.

In the Order, the President:

- Directs USDA to consider issuing **new rules under the Packers and Stockyards Act making it easier for farmers to bring and win claims, stopping chicken processors from exploiting and underpaying chicken farmers, and adopting anti-retaliation protections** for farmers who speak out about bad practices.
- Directs USDA to consider issuing **new rules defining when meat can bear "Product of USA" labels, so that consumers have accurate, transparent labels that enable them to choose products made here.**

- Directs USDA to develop a plan to **increase opportunities for farmers to access markets and receive a fair return, including supporting alternative food distribution systems like farmers markets and developing standards and labels** so that consumers can choose to buy products that treat farmers fairly.

- Encourages the FTC to **limit powerful equipment manufacturers from restricting people's ability to use independent repair shops or do DIY repairs—such as when tractor companies block farmers from repairing their own tractors**.

Internet Service

The Order tackles four issues that limit competition, raise prices, and reduce choices for internet service.

Lack of competition among broadband providers: More than 200 million U.S. residents live in an area with only one or two reliable high-speed internet providers, leading to prices as much as *five times higher* in these markets than in markets with more options. A related problem is landlords and internet service providers entering exclusivity deals or collusive arrangements that leave tenants with only one option. This impacts low-income and marginalized neighborhoods, because landlord-ISP arrangements can effectively block out broadband infrastructure expansion by new providers.

In the Order, the President encourages the FCC to:

- **Prevent ISPs from making deals with landlords that limit tenants' choices.**

Lack of price transparency: Even where consumers have options, comparison shopping is hard. According to the Federal Communications Commission (FCC), actual prices paid for broadband services can be 40% higher than advertised. During the Obama-Biden Administration, the FCC began developing a "Broadband Nutrition Label"—a simple label that provides basic information about the internet service offered so people can compare options. The Trump Administration FCC abandoned those plans.

In the Order, the President encourages the FCC to:

- **Revive the "Broadband Nutrition Label"** and **require providers to report prices and subscription rates** to the FCC.

High termination fees: If a consumer does find a better internet service deal, they may be unable to actually switch because of high early termination fees—on average nearly $200 —

charged by internet providers.

In the Order, the President encourages the FCC to:

- **Limit excessive early termination fees.**

Companies discriminatorily slowing down internet access: Big providers can use their power to discriminatorily block or slow down online services. The Obama-Biden Administration's FCC adopted "Net Neutrality" rules that required these companies to treat all internet services equally, but this was undone in 2017.

In the Order, the President encourages the FCC to:

- **Restore Net Neutrality rules** undone by the prior administration.

Technology

The Order tackles three areas in which dominant tech firms are undermining competition and reducing innovation:

Big Tech platforms purchasing would-be competitors: Over the past ten years, the largest tech platforms have acquired hundreds of companies—including alleged "killer acquisitions" meant to shut down a potential competitive threat. Too often, federal agencies have not blocked, conditioned, or, in some cases, meaningfully examined these acquisitions.

In the Order, the President:

- Announces an Administration policy of **greater scrutiny of mergers**, especially by dominant internet platforms, with particular attention to the acquisition of nascent competitors, serial mergers, the accumulation of data, competition by "free" products, and the effect on user privacy.

Big Tech platforms gathering too much personal information: Many of the large platforms' business models have depended on the accumulation of extraordinary amounts of sensitive personal information and related data.

In the Order, the President:

- Encourages the FTC to establish **rules on surveillance and the accumulation of data.**

Big Tech platforms unfairly competing with small businesses: The large platforms' power gives them unfair opportunities to get a leg up on the small businesses that rely on them to reach

customers. For example, companies that run dominant online retail marketplaces can see how small businesses' products sell and then use the data to launch their own competing products. Because they run the platform, they can also display their own copycat products more prominently than the small businesses' products.

In the Order, the President:

- Encourages the FTC to establish **rules barring unfair methods of competition on internet marketplaces.**

Cell phone manufacturers and others blocking out independent repair shops: Tech and other companies impose restrictions on self and third-party repairs, making repairs more costly and time-consuming, such as by restricting the distribution of parts, diagnostics, and repair tools.

In the Order, the President:

- Encourages the FTC to issue **rules against anticompetitive restrictions on using independent repair shops or doing DIY repairs** of your own devices and equipment.

Banking and Consumer Finance

Over the past four decades, the United States has lost 70% of the banks it once had, with around 10,000 bank closures. Communities of color are disproportionately affected, with 25% of all rural closures in majority-minority census tracts. Many of these closures are the product of mergers and acquisitions. Though subject to federal review, federal agencies have not formally denied a bank merger application in more than 15 years.

Excessive consolidation raises costs for consumers, restricts credit for small businesses, and harms low-income communities. Branch closures can reduce the amount of small business lending by about 10% and leads to higher interest rates. Even where a customer has multiple options, it is hard to switch banks partly because customers cannot easily take their financial transaction history data to a new bank. That increases the cost of the new bank extending you credit.

In the Order, the President:

- Encourages DOJ and the agencies responsible for banking (the Federal Reserve, the Federal Deposit Insurance Corporation, and the Office of the Comptroller of the Currency) to **update guidelines on banking mergers to provide more robust scrutiny of mergers**.

- Encourages the Consumer Financial Protection Bureau (CFPB) to issue **rules allowing customers to download their banking data** and take it with them.

###

Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids

A Proposed Rule by the Food and Drug Administration on 10/20/2021

This document has a comment period that ends in 15 days. (01/18/2022)

Read the 758 public comments

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ENHANCED CONTENT

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Supporting/Related Materials:
EA Reference 5 - Advancing Sustainable Materials Management RE... (https://www.regulations.gov/document?D=FDA-2021-N-0555-0148)
Reference 16 - The Potential Risk of Using PSAPs RE Medical... (https://www.regulations.gov/document?D=FDA-2021-N-0555-0146)
EA Reference 9 - FN - What are the benefits of rechargeable... (https://www.regulations.gov/document?D=FDA-2021-N-0555-0145)
PRIA Reference 6 - FDA Labeling Cost Model RE Medical Devices;... (https://www.regulations.gov/document?D=FDA-2021-N-0555-0143)
Proposed FONSI Environmental Assessment RE Medical Devices;... (https://www.regulations.gov/document?D=FDA-2021-N-0555-0141)
EA Reference 7 - FN - Universal Waste RE Medical Devices; Ear,... (https://www.regulations.gov/document?D=FDA-2021-N-0555-0140)
EA Reference 13 - FN - Hearing Aids Cost More Than Their... (https://www.regulations.gov/document?D=FDA-2021-N-0555-0139)
PRIA Reference 3 - Online Shopping and E-Commerce RE Medical... (https://www.regulations.gov/document?D=FDA-2021-N-0555-0138)
EA Reference 14 - FN - Duracell Hearing Aid Batteries RE... (https://www.regulations.gov/document?D=FDA-2021-N-0555-0137)
EA Reference 8 - FN - Mercury in Batteries RE Medical Devices;... (https://www.regulations.gov/document?D=FDA-2021-N-0555-0136)
See all 35 supporting documents (https://www.regulations.gov/docket/FDA-2021-N-0555/document?documentTypes=Supporting%20%26%20Related%20Material)

ENHANCED CONTENT

PUBLISHED DOCUMENT

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AGENCY:

Food and Drug Administration, HHS.

ACTION:

Proposed rule.

SUMMARY:

The Food and Drug Administration (FDA, we, or the Agency) is proposing to establish a regulatory category for over-the-counter (OTC) hearing aids and to make related amendments to update the regulatory framework for hearing aids. Specifically, we propose to define OTC hearing aids and establish applicable requirements; amend existing rules for consistency with a new OTC category; repeal the conditions for sale applicable to hearing aids; amend the existing labeling requirements for hearing aids; and update regulations relating to decisions on applications for exemption from Federal preemption that would become obsolete as a result of changes to the hearing aid requirements. This action, if finalized, would more clearly define prescription hearing aids; however, it would not change the classification of existing device types. In creating a regulatory category for OTC hearing aids and amending existing rules, we intend to provide reasonable assurance of safety and effectiveness for these devices as well as foster access to, and innovation in, hearing aid technology, thereby protecting and promoting the public health.

DATES:

Submit either electronic or written comments on the proposed rule by January 18, 2022. Submit written comments (including recommendations) on the collection of information under the Paperwork Reduction Act of 1995 by November 19, 2021.

ADDRESSES:

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 18, 2022. The *https://www.regulations.gov (https://www.regulations.gov)* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 18, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov (https://www.regulations.gov).* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov (https://www.regulations.gov)* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov (https://www.regulations.gov).*

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2021-N-0555 for "Establishing Over-the-Counter Hearing Aids." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *https://www.regulations.gov (https://www.regulations.gov)* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov (https://www.regulations.gov).* Submit both copies to

the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 (/select-citation/2021/10/20/21-CFR-10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469 (/citation/80-FR-56469), September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf (https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf).*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov (https://www.regulations.gov)* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

Submit comments on information collection issues under the Paperwork Reduction Act of 1995 (PRA) to the Office of Management and Budget (OMB) at *https://www.reginfo.gov/public/do/PRAMain (https://www.reginfo.gov/public/do/PRAMain).* Find this particular information collection by selecting "Currently under Review—Open for Public Comments" or by using the search function. The title of this proposed collection is "Medical Device Labeling Regulations."

FOR FURTHER INFORMATION CONTACT:

Srinivas Nandkumar, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD, 20993, 301-796-5620, *Srinivas.Nandkumar@fda.hhs.gov (mailto:Srinivas.Nandkumar@fda.hhs.gov).*

With regard to the information collection: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, *PRAStaff@fda.hhs.gov (mailto:PRAStaff@fda.hhs.gov).*

SUPPLEMENTARY INFORMATION:

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Executive Summary

Purpose of the Proposed Rule

Hearing loss affects an estimated 30 million people in the United States and can have a significant impact on communication, social participation, and overall health and quality of life. Despite the high prevalence and public health impact of hearing loss, only about one-fifth of people who could benefit from a hearing aid seek

intervention. Several barriers likely impede the use of hearing aids in hearing-impaired individuals such as high cost, stigma of being perceived as old or debilitated, and value (perceived hearing benefit relative to price). FDA is proposing rules to address some of these concerns.

Moreover, the FDA Reauthorization Act of 2017 (FDARA) directs FDA to establish a category of OTC hearing aids through rulemaking, and FDARA sets forth various requirements for OTC hearing aids, including preemption provisions. In addition to protecting and promoting the public health, we have developed these proposed rules to establish the OTC category and implement the requirements of FDARA.

Summary of the Major Provisions of the Proposed Rule

FDA is proposing to establish a regulatory category for OTC hearing aids to improve access to hearing aid technology for Americans. OTC hearing aids will be intended to address perceived mild to moderate hearing loss in people age 18 or older. Alongside the OTC category, we are proposing multiple related changes to the overall regulatory framework for hearing aids to harmonize existing rules with the eventual OTC category. We believe the proposals set forth in this rulemaking will protect the public health by providing reasonable assurance of safety and effectiveness for hearing aids, as well as promote the hearing health of Americans by lowering barriers to access and fostering innovation in hearing aid technology.

Among other things, FDARA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by defining OTC hearing aids and providing the authorities to establish the OTC category of hearing aids among provisions that are, by definition, general controls. We are proposing general controls for OTC hearing aids consistent with FDARA. Moreover, because the FD&C Act specifies that OTC hearing aids are those that use the same fundamental scientific technology as air-conduction hearing aids, we would realign the existing classification regulations for hearing aids by sound conduction technology. However, the realignment would not affect the device class or premarket notification exemption status of any existing device. On the effective date of the final rule, we would realign current product codes to correspond with the revised regulations for consistency but would not otherwise change the codes.

This rulemaking also affects other existing regulations that apply to hearing aids. FDA has established device restrictions for hearing aids that include labeling requirements as well as conditions for sale. We are proposing to remove these device restrictions for hearing aids, and establish a new regulation for prescription hearing aid labeling. Further, FDA has by regulation granted or denied exemptions from Federal preemption for State requirements pertaining to hearing aids. The removal of the device restrictions on hearing aids, as well as certain provisions of FDARA, impact most of these previous exemption decisions, for example, by altering their scope. We are proposing to remove the regulations codifying these decisions and establish other regulations clarifying some of the effects of statutory preemption under FDARA.

Legal Authority

The FD&C Act establishes a comprehensive system for the regulation of devices intended for human use. Hearing aids are devices intended for human use and so are subject to, among other requirements, the device provisions of the FD&C Act. FDA has authority to establish regulatory controls needed to provide reasonable assurance of safety and effectiveness for these devices. As such, FDA is establishing regulatory controls for OTC hearing aids and amending regulatory controls for prescription hearing aids.

Specific to OTC hearing aids, the FD&C Act and FDARA authorize multiple controls, including authority for FDA to establish requirements for device labeling, output limits, conditions for sale and distribution, and other requirements that provide reasonable assurance of safety and effectiveness of OTC hearing aids. FDARA specifically directs FDA to establish a category of OTC hearing aids by regulation that must include the aforementioned requirements.

More generally, the FD&C Act further provides for labeling requirements as general controls such that devices (and other medical products) will not be misbranded. The FD&C Act also authorizes FDA to issue regulations for the efficient enforcement of the FD&C Act. We are proposing the following regulations

pursuant to these authorities and to fulfill the directive under FDARA.

Additionally, both the FD&C Act and FDARA include preemption provisions applicable to hearing aids.

Costs and Benefits

This proposed rule to establish OTC hearing aids and align other regulations, if finalized, would generate potential cost savings for consumers with perceived mild to moderate hearing loss who wish to buy lower cost hearing aids not bundled with professional services and not requiring professional advice, fitting, adjustment, or maintenance but who are currently unable to buy such products online because of State regulations or because they do not shop online. The proposed rule, if finalized, would also generate costs for hearing aid manufacturers for changing labeling of existing hearing aids as well as for reading the rule and revising internal standard operating procedures in response to the rule. We estimate benefits of between $6 million and $147 million per year based on 5th and 95th percentile Monte Carlo results with a mean of $63 million per year. We estimate annualized costs of between $1 million and $2 million per year based on 5th and 95th percentile Monte Carlo results with a mean of $1 million per year. Combining benefits and costs, we used Monte Carlo analysis to estimate annualized net benefits of between $5 million and $145 million per year based on the 5th and 95th Monte Carlo percentile results with a mean of $62 million per year at both 3 percent and 7 percent discount rates.

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Table of Abbreviations and Acronyms Commonly Used in This Document

Abbreviation/acronym	What it means
510(k)	A premarket notification for certain devices.
ANSI	American National Standards Institute.
ASA	Acoustical Society of America.
CFR	Code of Federal Regulations.
CTA	Consumer Technology Association.
dB	Decibel.
dBA	A-weighted decibel.
EA	Environmental assessment.
FDA	Food and Drug Administration.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FDARA	FDA Reauthorization Act of 2017.
FONSI	Finding of no significant impact.
FR	Federal Register.
GMPs	Good manufacturing practices.
Hz	Hertz.
ISO	International Organization for Standardization.
MSW	Municipal solid waste.
NASEM	National Academies of Sciences, Engineering, and Medicine.
NIOSH	National Institute for Occupational Safety and Health.
OMB	Office of Management and Budget.
OSPL90	Output sound pressure level with 90-dB input.
OTC	Over-the-counter.
PCAST	President's Council of Advisors on Science and Technology.
PRIA	Preliminary Regulatory Impact Analysis.
PSAP	Personal sound amplification product.
Pub. L	Public Law.
QS	Quality System.
SPL	Sound pressure level.
U.S.C	United States Code.

I. Background

FDA is proposing to define and establish general controls for an OTC category of hearing aids. We intend these proposals to provide for reasonable assurance of safety and effectiveness for these devices and improve access to and foster innovation in hearing aid technology for Americans, thereby promoting and protecting the public health. We would make various other revisions, as described in this document, to align existing regulations with statutory requirements and the new OTC category.

A. Need for the Regulation

Hearing loss affects an estimated 30 million people in the United States and can have a significant impact on communication, social participation, and overall health and quality of life (Refs. 1 and 2). Despite the high prevalence and public health impact of hearing loss, only about one-fifth of people who could benefit from a hearing aid seek intervention (Ref. 3). The use of hearing aids has been linked to, among other health benefits, reductions in the incidence or severity of cognitive decline, depression, and other health problems in older adults (Ref. 3a and 3b). Additionally, benefits of hearing aid use can include improved social participation and a better quality of life.

Besides health benefits for individuals, more-widespread adoption of hearing aids could have broader effects. By increasing social participation, hearing aids could help to improve inclusion of individuals in family, economic, civic, and religious life. Thus, reducing barriers to hearing aid access might contribute to such improvements. This could be particularly true for people of color, rural Americans, low-income individuals, and others for whom barriers to hearing aid access may be especially burdensome.

Several barriers likely impede the use of hearing aids in hearing-impaired individuals such as high cost, stigma of being perceived as old or debilitated, and value (perceived hearing benefit relative to price) (Ref. 4). In addition, stakeholders have cited Federal regulations that require specific labeling and conditions for sale, initially implemented in the late 1970s, as barriers to access (*e.g.,* Refs. 5 to 7). This document proposes a number of changes to the regulatory framework for hearing aids to remove or reduce barriers to certain air-conduction hearing aids for perceived mild to moderate hearing impairment—a type of impairment often associated with aging—that have the potential to be of great benefit to the public health.

These proposals follow the enactment of FDARA, which included provisions directing FDA to establish regulatory requirements for a new category of OTC hearing aids and amended the FD&C Act to add section 520(q) (21 U.S.C. 360 (https://www.govinfo.gov/link/uscode/21/360?type=usc&year=mostrecent&link-type=html)j(q); see Pub. L. 115-52 (https://www.govinfo.gov/link/plaw/115/public/52?link-type=html)). Section 520(q)(1) of the FD&C Act defines OTC hearing aids, in part, as devices available over-the-counter, without the supervision, 🗋 prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online. Section 520(q)(2) of the FD&C Act requires that such devices be subject to the regulations FDA issues for them in accordance with section 709(b) of FDARA.

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Section 709(b) of FDARA requires that FDA establish a category of OTC hearing aids that includes, among other elements, requirements to provide reasonable assurances of the safety and effectiveness of these devices. We also make multiple proposals to prevent the sale of OTC hearing aids to or for people younger than age 18. This document does not, however, propose to create or classify a new device type.[1] Further, this document does not propose to exempt additional devices from the premarket notification requirements under section 510(k) of the FD&C Act, commonly referred to as "a 510(k)" (21 U.S.C. 360 (https://www.govinfo.gov/link/uscode/21/360?type=usc&year=mostrecent&link-type=html)(k)). Section IV of this document discusses our findings regarding premarket notification in more detail.

We are simultaneously proposing related changes to the regulatory framework that currently applies to all hearing aids, as they are defined in § 801.420 (21 CFR 801.420 (/select-citation/2021/10/20/21-CFR-801.420)), in light of the new OTC category and to ensure consistency across rules pertaining to hearing aids (see § 801.420(a)(1)). Detailed information about each proposal appears in section III.

B. Current Regulatory Framework for Hearing Aids

Hearing aids, as defined in § 801.420(a)(1), are currently restricted class I and class II devices of multiple types. A summary of the current regulatory framework for these devices appears in table 1.

Table 1—Summary of Current Regulatory Framework

Classification regulation, 21 CFR section	874.3300	874.3305	874.3315	874.3325	874.3950
Device Restrictions	Restricted	Restricted	Restricted	Restricted	Restricted.
Class I, 510(k) exempt [1]	Air-conduction ("legacy")				
Class II, 510(k) exempt [1]		Wireless air-conduction			
Class II	Bone-conduction		Tympanic membrane contact hearing aid	Self-fitting air-conduction	Transcutaneous air-conduction hearing aid system.
Product codes	ESD, LXB, MAH, LRB, LDG	OSM	PLK	QDD	NIX.

[1] *510(k) exemptions are subject to the limitations in 21 CFR 874.9 (/select-citation/2021/10/20/21-CFR-874.9).*

1. HEARING AID CLASSIFICATIONS

Hearing aids are class I and class II wearable sound-amplifying devices intended to compensate for impaired hearing. They currently fall under five classification regulations (the following references are to sections in Title 21 of the CFR):

a. Hearing aid (§ 874.3300 (21 CFR 874.3300 (/select-citation/2021/10/20/21-CFR-874.3300))). This device type includes air-conduction (class I, 510(k) exempt, subject to the limitations of exemption in § 874.9) and bone-conduction (class II) hearing aids. Class II bone-conduction hearing aids require a 510(k) notification. These are all restricted devices.

b. Wireless air-conduction hearing aid (§ 874.3305 (21 CFR 874.3305 (/select-citation/2021/10/20/21-CFR-874.3305))). This device type is a hearing aid that incorporates wireless technology in its programming or use, for example, controls over Bluetooth. These devices are class II restricted, subject to the special controls that have been issued for these devices, and 510(k) exempt, subject to the limitations of exemption in § 874.9.

c. Tympanic membrane contact hearing aid (§ 874.3315 (21 CFR 874.3315 (/select-citation/2021/10/20/21-CFR-874.3315))). This device type is a prescription device that compensates for impaired hearing. Amplified sound is transmitted by vibrating the tympanic membrane through a transducer that is in direct contact with the tympanic membrane. These devices are class II restricted, subject to the special controls that have been issued for these devices, and require a 510(k) notification.

d. Self-fitting air-conduction hearing aids (§ 874.3325 (21 CFR 874.3325 (/select-citation/2021/10/20/21-CFR-874.3325))). This device type is a hearing aid that incorporates technology, including software, that allows users to program their hearing aids. This technology integrates user input with a self-fitting strategy

and enables users to independently derive and customize their hearing aid fittings and settings. These devices are class II restricted, subject to the special controls that have been issued for these devices, and require a 510(k) notification.

e. Transcutaneous air conduction hearing aid system (§ 874.3950 (21 CFR 874.3950 (/select-citation/2021/10/20/21-CFR-874.3950))). This device type consists of an air-conduction hearing aid attached to a surgically fitted tube system, which is placed through soft tissue between the post auricular region and the outer ear canal. These devices are class II restricted, subject to the special controls that have been issued for these devices, and require a 510(k) notification.

Devices of these types may be either prescription (for example, devices for insertion deep in the ear canal) or non-prescription devices (which include the majority of air-conduction hearing aids).[2] For the purposes of this rulemaking, we refer to non-wireless, non-self-fitting, air-conduction hearing aids as "legacy hearing aids," which means all air-conduction hearing aids currently within § 874.3300 but not air-conduction hearing aids currently within §§ 874.3305, 874.3325, or 874.3950.

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2. HEARING AID RESTRICTIONS

Hearing aids are currently subject to a set of restrictions on sale, distribution, and use, established in accordance with section 520(e) of the FD&C Act. We will refer to those as "Hearing Aid Restrictions," and they include requirements for professional and patient labeling, as a well as conditions for sale (see §§ 801.420 and 801.421 (21 CFR 801.420 (/select-citation/2021/10/20/21-CFR-801.420) and 801.421, respectively)). All legacy hearing aids, wireless air-conduction hearing aids, and self-fitting hearing aids (as well as other device types) fall within a separate, broader definition of hearing aids in § 801.420(a)(1), and therefore are currently subject to these restrictions.

Among other requirements, § 801.420 specifies that the User Instructional Brochure labeling for hearing aids contain a warning statement for hearing aid dispensers that prompts them to advise prospective purchasers to consult with a physician if any of the listed medical conditions are present (see § 801.420(c)(2)). We will refer to these medical conditions as "red flag" conditions in this proposal. The rule further prescribes a notice to prospective users and an additional statement about hearing loss in children (see § 801.420(c)(3)). It also requires the disclosure of technical data useful in selecting, fitting, and checking the performance of hearing aids (see § 801.420(c)(4)).

Currently, § 801.421 specifies a number of conditions for sale for hearing aids. Such conditions include that a prospective user must present to the dispenser a signed statement of medical evaluation from a physician prior to sale (see § 801.421(a)(1)). However, a prospective user who is 18 years of age or older may waive the medical evaluation requirement by signing a statement with a prescribed advisement (see § 801.421(a)(2)). A dispenser must provide an opportunity for the prospective user to review the User Instructional Brochure prior to signing a waiver and the sale of a hearing aid (see § 801.421(b)). Manufacturers and distributors must provide sufficient copies of User Instructional Brochures to dispensers, and upon written request, to prospective users; dispensers must similarly provide the brochures (or the name and address of a manufacturer or distributor to obtain a brochure) to prospective users upon request (see § 801.421(c)). Dispensers generally must retain a copy of a medical evaluation statement or signed waiver for 3 years (see § 801.421(d)).

However, we announced in a guidance entitled "Conditions for Sale for Air-Conduction Hearing Aids" that we do not intend to enforce the medical evaluation, waiver, or recordkeeping requirements of § 801.421 with respect to prospective purchasers who are 18 or older (Ref. 8).

In addition to other applicable misbranding and adulteration provisions in sections 501 and 502 of the FD&C Act (21 U.S.C. 351 (https://www.govinfo.gov/link/uscode/21/351?type=usc&year=mostrecent&link-type=html) and 21 U.S.C. 352 (https://www.govinfo.gov/link/uscode/21/352?

type=usc&year=mostrecent&link-type=html), respectively), hearing aids are currently subject to misbranding provisions for restricted devices under section 502(q) and (r) of the FD&C Act. Section 704(a) of the FD&C Act (21 U.S.C. 374 (https://www.govinfo.gov/link/uscode/21/374?type=usc&year=mostrecent&link-type=html)(a)) authorizes FDA to inspect, among other things, certain records relating to restricted devices.

3. STATE REQUIREMENTS FOR HEARING AIDS

Under certain circumstances, State requirements apply to hearing aids notwithstanding Federal requirements. In general, FDA's regulation of hearing aids preempts State law, meaning that a State or a political subdivision (*e.g.,* a city) may not establish or continue in effect its own requirement if that requirement is "different from, or in addition to," a requirement under the FD&C Act (see section 521(a) (21 U.S.C. 360 (https://www.govinfo.gov/link/uscode/21/360?type=usc&year=mostrecent&link-type=html)k(a))). Many States have established requirements equivalent to § 801.420 or § 801.421 (*i.e.,* not "different from, or in addition to" those regulations), which are not preempted by these Federal requirements.

However, for other State requirements, FDA has granted and denied exemptions from preemption under section 521(b) of the FD&C Act for some States that have applied. FDA responds to applications for such exemptions by regulation, codified in subpart C of part 808 (21 CFR part 808 (/select-citation/2021/10/20/21-CFR-808)). Most of these regulations relate to hearing aids, and in some of these regulations, FDA has granted exemptions—meaning those States' requirements apply instead of, or in addition to, FDA's requirements—for:

- Specifying the physician expertise needed to examine prospective purchasers who are younger than 18 years of age;
- Advising purchasers when to seek medical attention based on "red flag" conditions;
- Providing purchasers with certain information and disclosures on receipts and other documentation;
- Recordkeeping requirements in addition to the Hearing Aid Restrictions; and
- Providing written notice of a money-back guarantee where a State court held the State requirement was preempted.

And FDA has denied exemptions—meaning the States could not establish or continue in effect requirements —for:

- Removing the waiver option for prospective purchasers who are 18 years of age or older;
- Lowering the age at which a waiver of medical examination prior to purchase was available;
- Changing the expertise for examinations, when conducted, for people 18 years of age and older;
- Prohibiting certain marketing claims about improving hearing; and
- Adopting different device testing standards.

FDARA added a separate Federal preemption provision for State and local laws, regulations, orders, or other requirements (for brevity, we will refer to "State or local requirements" in this rulemaking) specifically related to hearing products (FDARA section 709(b)(4)).[3] That provision may affect the applicability of State or local requirements for OTC hearing aids. Section III.G discusses the OTC hearing aid preemption provisions and the effects of this rulemaking.

4. HEARING PRODUCTS NOT REGULATED AS HEARING AIDS

FDA does not consider personal sound amplification products (PSAPs) to be "devices" within the meaning of section 201(h) of the FD&C Act (21 U.S.C. 321 (https://www.govinfo.gov/link/uscode/21/321?type=usc&year=mostrecent&link-type=html)(h)) when they are not intended to aid a person with, or compensate for, impaired hearing and do not otherwise meet the device definition. Such PSAPs are not subject to medical device regulations, nor would the proposed requirements of this rulemaking apply to such

PSAPs.[4] Note that the name of a product on its own would not ordinarily demonstrate intended use. Thus, merely calling a product something besides "hearing aid" would not remove a product from device regulation under the FD&C Act if, for example, its labeling demonstrated that the product was intended to compensate for hearing loss.

C. History of This Rulemaking

Although this proposal is the first step in this rulemaking, FDA has taken other steps to initiate an update of the regulatory framework for hearing aids. Prior to the enactment of FDARA, FDA had considered means to improve access to hearing aids. For example, we considered a report on the public health implications of hearing loss in adults that made recommendations to improve affordability and accessibility of hearing aids and to foster innovative hearing aid technology. The October 2015 report by the President's Council of Advisors on Science and Technology (PCAST) recommended, among other actions, that, "FDA should approve [a] class of hearing aids for over-the-counter (OTC) sale, without the requirement for consultation with a credentialed dispenser" (Ref. 7). In addition, the report concluded, among other things, that the Federal requirement for a medical examination, or a written waiver of such examination, "provides little patient benefit, while acting as a barrier to access for the millions of Americans needing hearing assistance" (Ref. 7).

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Similarly, FDA, other Federal Agencies, and a consumer advocacy group co-sponsored a study entitled "Hearing Health Care for Adults: Priorities for Improving Access and Affordability" through the National Academies of Sciences, Engineering, and Medicine (NASEM). The resulting NASEM report, published on June 2, 2016, similarly recommends that FDA create a new category of OTC "wearable hearing devices" (using a term distinct from "hearing aids") and also that FDA remove the medical evaluation requirement for adults for hearing aids (Ref. 6). After a review of the literature and relevant clinical databases from the U.S. Department of Defense and the U.S. Department of Veterans Affairs, NASEM concluded that the health risk of missed diagnosis of treatable causes of hearing loss in adults is low, and "[the] regulation [requiring a medical examination or waiver] provides no clinically meaningful benefit, and the waiver presents a barrier to access with no substantial enhancement of patient safety."

Both PCAST and NASEM provided recommendations regarding FDA Quality System requirements (which set forth requirements for good manufacturing practices or GMPs) for the proposed category of OTC hearing aids. PCAST stated the following:

FDA should exempt this class of hearing aids from QSR regulation in its present form and substitute compliance with standards for product quality and recordkeeping appropriate for the consumer-electronics industry, developed by an appropriate third-party organization and approved by FDA. Similar actions should be taken with respect to diagnostic hearing tests used to dispense and fit Class I hearing aids.

However, NASEM recommended that these devices "[b]e subject to quality system regulation (QSR) requirements, but be considered for exemption from certain QSR requirements as determined by FDA to be appropriate for this category."

We held a public workshop on April 21, 2016, entitled "Streamlining Regulations for Good Manufacturing Practices (GMPs) for Hearing Aids," (announced at 81 FR 784 (/citation/81-FR-784); see Ref. 9 for materials). FDA requested comments on several topics relating to hearing healthcare technology and improved access, including the appropriate level of GMP regulation (Quality System requirements) to ensure the safety and effectiveness of air-conduction hearing aid devices in consideration of the PCAST report recommendations.

FDA received hundreds of comments to the docket for this workshop prior to the (extended) deadline of June 30, 2016. In addition, 2 keynote speakers (from PCAST and NASEM), 12 invited speakers, and 24 public speakers offered comments or presentations at the workshop. Workshop speakers and submitters of docket

comments were generally: Healthcare professionals (or healthcare professional organizations), members of industry, patients or consumers, academics, consensus standards developers, and science organizations.

Comments from this workshop ranged generally from strong opposition to strong support for the PCAST recommendations. Other comments were more nuanced. To summarize very broadly, all parties agreed that some combination of regulatory requirements and flexibility in compliance would provide reasonable assurance of safety and effectiveness. The differences in opinion lie in the preferred approach and its implementation to achieve these common goals. For example, some preferred amending the QS regulation and relying on inspections while others preferred allowing voluntary conformity to a consensus standard potentially relying on third-party certification.

In another effort to address the current regulatory framework, FDA also issued a guidance document, as noted above, related to the conditions for sale for air-conduction hearing aids. In that document, we announced our intent to reexamine and modify § 801.421 based on the PCAST and NASEM recommendations, as well as from other stakeholders, taking into consideration and addressing their recommendations as appropriate before adopting regulations for OTC hearing aids. The docket no. FDA-2016-D-3466 included commentary that expressed support for the creation of a "basic" category of hearing aids such as OTC hearing aids and provided recommendations for measures to support safe and effective use. We also received multiple telephone calls expressing similar interest in reducing regulatory burdens and questioning how the issuance of the guidance affected States' requirements.

In developing this proposed rule, we considered the input and questions we have received on the guidance, as well as the comments from the April 2016 public workshop and the recommendations from PCAST and NASEM.

D. Incorporation by Reference

FDA is proposing to incorporate by reference the Method and tables for clause 4.1 of ANSI/CTA-2051, "Personal Sound Amplification Performance Criteria," dated January 2017, from the American National Standards Institute, 1889 L Street NW, 11th floor, Washington, DC 20036; *https://www.ansi.org (https://www.ansi.org),* 202-293-8020. You may download the standard from the web at *https://webstore.ansi.org/standards/ansi/cta20512017ansi (https://webstore.ansi.org/standards/ansi/cta20512017ansi).* The Method and tables for clause 4.1 describe how to measure frequency response and include technical data for adaptations for different circumstances. The Method and tables would provide a standardized way to quantify frequency response for OTC hearing aids and meet the related proposed requirements (see section III.E.1).

FDA is also proposing to incorporate by reference ANSI/ASA S3.22-2014, "Specification of Hearing Aid Characteristics," dated November 2014, from the American National Standards Institute, 1889 L Street NW, 11th floor, Washington, DC 20036; *https://www.ansi.org (https://www.ansi.org),* 202-293-8020. ANSI/ASA S3.22-2014 describes tolerances and test methods used for certain measurements of hearing aid performance. The application of ANSI/ASA S3.22-2014 provides professional hearing aid fitters with standardized technical information to help them select the correct hearing aid and ensure optimal fit and performance for hearing aid users (see section III.H.2).

II. Legal Authority

The FD&C Act establishes a comprehensive system for the regulation of devices, as defined in section 201(h) of the FD&C Act, intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360 (https://www.govinfo.gov/link/uscode/21/360?type=usc&year=mostrecent&link-type=html)c) defines three classes of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three classes of devices are class I (general controls), class II (special controls), and class III (premarket approval) (see 21 U.S.C. 360 (https://www.govinfo.gov/link/uscode/21/360?type=usc&year=mostrecent&link-type=html)c). Hearing aids are devices intended for human use and are subject to the FD&C Act. Currently, air-conduction hearing aids are generally either class I or class II devices.

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FDARA amended the FD&C Act to apply requirements specific to certain hearing aids and defined the term "over-the-counter hearing aid" (see 21 U.S.C. 360 (https://www.govinfo.gov/link/uscode/21/360?type=usc&year=mostrecent&link-type=html)j(q)). We are issuing these requirements for OTC hearing aids pursuant to section 709(b) of FDARA, which authorizes FDA to establish requirements for labeling, output limits, conditions for sale and distribution of OTC hearing aids, and other requirements that provide for reasonable assurance of safety and effectiveness of these devices.

In addition, the FD&C Act provides that a device is misbranded unless, among other requirements, its labeling bears adequate directions for use (see section 502(f)(1) of the FD&C Act). Consistent with section 502 of the FD&C Act, FDA has issued regulations that exempt certain kinds of devices from the requirement for adequate directions for use. Section 502(f)(2) further requires adequate warnings against use of a device in those pathological conditions, or by children, where use of the device may be dangerous to health. The labeling must also bear adequate warnings against unsafe dosage or methods or duration of administration or application (see section 502(f)(2) of the FD&C Act). Such warnings must be in such manner and form as are necessary for the protection of the users (see section 502(f)(2) of the FD&C Act).

A device is also misbranded if its labeling is false or misleading in any particular (see section 502(a) of the FD&C Act). Section 201(n) of the FD&C Act states that in determining whether labeling or advertising is misleading, there shall be taken into account not only representations made or suggested but also the extent to which labeling or advertising fails to reveal material facts.

Other misbranding provisions under the FD&C Act would apply as well, including section 502(c), which deems a device to be misbranded if any word, statement, or other information required by or under authority of the FD&C Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

Additionally, section 701(a) of the FD&C Act authorizes FDA to issue regulations for the efficient enforcement of the FD&C Act (21 U.S.C. 371 (https://www.govinfo.gov/link/uscode/21/371?type=usc&year=mostrecent&link-type=html)(a)). The proposals in this rulemaking would be for the efficient enforcement of the FD&C Act because, if finalized, they will provide standards for the legal marketing of safe and effective hearing aid devices.

Violations of any final rules from this rulemaking, once in effect, would render the hearing aids adulterated and/or misbranded under sections 501 and/or 502 of the FD&C Act, and subject to enforcement action, for example, seizure (see section 304 of the FD&C Act (21 U.S.C. 334 (https://www.govinfo.gov/link/uscode/21/334?type=usc&year=mostrecent&link-type=html))), injunction (see section 302 of the FD&C Act (21 U.S.C. 332 (https://www.govinfo.gov/link/uscode/21/332?type=usc&year=mostrecent&link-type=html))), and criminal prosecution (see section 303 of the FD&C Act (21 U.S.C. 333 (https://www.govinfo.gov/link/uscode/21/333?type=usc&year=mostrecent&link-type=html))). Prohibited acts include, among others, introducing an adulterated or misbranded device into interstate commerce (see section 301 of the FD&C Act (21 U.S.C. 331 (https://www.govinfo.gov/link/uscode/21/331?type=usc&year=mostrecent&link-type=html))).

Under section 521 of the FD&C Act, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement that is different from, or in addition to, any requirement applicable under the FD&C Act to the device and that relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the FD&C Act (21 U.S.C. 360 (https://www.govinfo.gov/link/uscode/21/360?type=usc&year=mostrecent&link-type=html)k). Section 521 of the FD&C Act also provides that FDA may grant an exemption from preemption under certain circumstances. Section 709(b) of FDARA also includes a preemption provision with respect to requirements for OTC hearing aids.

III. Description of the Proposed Rule

We are proposing multiple related actions in this rulemaking:

- Add to part 800, subpart B (21 CFR part 800 (/select-citation/2021/10/20/21-CFR-800), subpart B), definitions and other rules for OTC hearing aids;
- Remove § 801.420 and repeal § 801.421;
- Add to part 801, subpart H (21 CFR part 801 (/select-citation/2021/10/20/21-CFR-801), subpart H), § 801.422, labeling requirements for prescription hearing aids;
- Amend part 874, subpart D (21 CFR part 874 (/select-citation/2021/10/20/21-CFR-874), subpart D), in multiple places to update classification regulations for hearing aids and align hearing aid types by sound-conduction technology; and
- Amend part 808, subparts A and C (21 CFR part 808 (/select-citation/2021/10/20/21-CFR-808), subparts A and C), by updating the Scope and removing most of the current regulations codifying previous decisions for exemption from Federal preemption for certain States.

If this action is finalized, all non-OTC hearing aids will be prescription devices and would be subject to the labeling requirements in new § 801.422 as well as those in the existing § 801.109, but they would no longer be restricted devices. Note that a prescriber is any practitioner licensed by the law of the State in which the practitioner practices to use, or order the use of, the device. When the prescriber of a hearing aid need not be a physician, the labeling of a prescription hearing aid will describe other prescribers, for example, audiologists (see § 801.109(b)(1)).

We believe the proposed actions will, in combination, promote and protect the public health by, among other things, providing reasonable assurance of safety and effectiveness of OTC and prescription hearing aids. These actions would also help minimize the complexity of the applicable regulations, if finalized, through organization. We are proposing to add the OTC Hearing Aid Controls to 21 CFR part 800 (/select-citation/2021/10/20/21-CFR-800), subpart B, entitled "Requirements for Specific Medical Devices," which would make them easy to locate. Labeling requirements for prescription devices would remain in part 801, Labeling, subpart H, "Special Requirements for Specific Devices." Table 2 outlines the proposed hearing aid rules. Section III.I summarizes the proposed revisions to part 808.

Table 2—Outline of Proposed Hearing Aid Rule

800.30	801.422	874.3301	874.3305
Over-the-counter hearing aid controls [1]	**Prescription hearing aid labeling [1]**	**Bone-conduction hearing aid**	**Air-conduction hearing aid**
(a) Scope.	(a) Scope.	(a) Identification.	(a) Identification.
(b) Definitions.	(b) Definitions.	(b) Classification.	(b) Classification.
(c) Labeling.	(c) Labeling.	Product codes LXB, MAH.	• Legacy.
• Package.	• Package.		• Wireless.
• Labeling Inside the Package.	• Labeling Inside the Package.		• Self-Fitting.
• Labeling on the Device.	• Labeling on the Device.		Product codes ESD, OSM, QDD,
• Technical Specifications.	• Technical Specifications.		LRB, and LDG.
	• Misbranding.		

[1] *These requirements would apply in addition to all other applicable requirements, including applicable labeling requirements in parts 801 and 830 (21 CFR parts 801 (/select-citation/2021/10/20/21-CFR-801) and 830). For example, for prescription devices, the labeling requirements in § 801.109 would continue to apply in addition to new § 801.422.*

800.30	801.422	874.3301	874.3305
Over-the-counter hearing aid controls [1]	**Prescription hearing aid labeling [1]**	**Bone-conduction hearing aid**	**Air-conduction hearing aid**
(d) Output Limits.	(d) Incorporation by Reference.		
(e) Electroacoustic Performance.			
• Distortion Control.			
• Self-generated Noise.			
• Latency.			
• Bandwidth.			
• Smoothness.			
(f) Design Requirements.			
• Insertion Depth.			
• Atraumatic Materials.			
• Proper Fit.			
• Tools, Tests, or Software.			
(g) Condition for Sale.			
(h) Effect on State Law.			
(i) Incorporation by Reference.			

[1] *These requirements would apply in addition to all other applicable requirements, including applicable labeling requirements in parts 801 and 830 (21 CFR parts 801 (/select-citation/2021/10/20/21-CFR-801) and 830). For example, for prescription devices, the labeling requirements in § 801.109 would continue to apply in addition to new § 801.422.*

A. Scope (Proposed § 800.30(a))

The regulation would clarify which devices are subject to the OTC Hearing Aid Controls. Among other changes, FDARA amended the FD&C Act to define the term "over-the-counter hearing aid," and section 709 of FDARA directs FDA to establish certain requirements for labeling, output limits, conditions for sale, and other requirements that provide reasonable assurances of the safety and effectiveness of OTC hearing aids. We propose to call this set of requirements "Over-the-Counter Hearing Aid Controls" and add § 800.30 to establish the OTC category of hearing aids and their requirements.

The scope, proposed paragraph (a), would specify the devices to which the regulation would apply, assisting with the determination of applicable requirements. This provision clarifies that a hearing aid is either in the prescription or OTC category and that, regardless of category, special controls found in the applicable classification regulation and other requirements in the FD&C Act apply.

B. Definitions (Proposed §§ 800.30(b) and 801.422(b))

FDA proposes to include the definition of an OTC hearing aid, consistent with the definition in section 520(q)(1) of the FD&C Act, and the definitions of other terms integral to understanding § 800.30. In several cases, we are proposing parallel definitions (sometimes slightly modified) under the proposed requirements for prescription hearing aid labeling in § 801.422.

Defining hearing aids. FDARA authorizes controls for devices that, among other characteristics, use the same fundamental scientific technology as air-conduction hearing aids under §§ 874.3300 or 874.3305. Section 520(q)(1)(A)(i) of the FD&C Act does not specifically refer to § 874.3325 because, at the time of

FDARA's enactment, FDA had not classified that device type. However, we consider self-fitting hearing aids currently classified under § 874.3325 to be eligible for regulation as OTC hearing aids.

We consider them as such because, although self-fitting hearing aids under § 874.3325 differ from hearing aids under §§ 874.3300 and 874.3305 in that they incorporate technology, including software, that allows users to program their hearing aids, self-fitting hearing aids use the same air-conduction technology as hearing aids under §§ 874.3300 and 874.3305. Self-fitting hearing aids also meet the other elements of the OTC hearing aid definition in section 520(q)(1)(A) of the FD&C Act. For example, self-fitting hearing aids, through tools, tests, or software, allow the user to control the hearing aid and customize it to the user's hearing needs (see section 520(q)(1)(A)(iii) of the FD&C Act).

The proposed definitions of "hearing aid" (which is the current definition), "air-conduction hearing aid," "over-the-counter hearing aid," and "prescription hearing aid" help to delineate the different device categories.[5] As stated in section 520(q)(1)(B) of the FD&C Act, the definition of "over-the-counter hearing aid" does not include PSAPs. Similarly, the definition of "hearing aid" more generally excludes PSAPs that are not intended to aid with or compensate for impaired hearing. The proposed definition of "prescription hearing aid" in proposed § 801.422 is the same as that in the OTC Hearing Aid Controls except that the definition for prescription devices would cross-reference the OTC Hearing Aid Controls, proposed § 800.30.

Defining licensed persons. In that vein, OTC hearing aids will be available without the supervision, prescription, or other order, involvement, or intervention of a licensed person (section 520(q)(1)(A)(v) of the FD&C Act). A definition of "licensed person" would help delineate that a patient or consumer of OTC hearing aids will not need to consult an audiologist, a physician, or other licensed person prior to or after purchasing an OTC hearing aid. The proposed definition of "licensed person" also clarifies that FDA interprets "licensed person" to include businesses consistent with the broad definition of "person" in section 201(e) of the FD&C Act. For example, OTC hearing aids may be available for sale from businesses that are not specially licensed to distribute OTC hearing aids.[6]

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FDA does not interpret section 520(q)(1)(A)(v) of the FD&C Act or section 709(b) of FDARA as preempting a State's ability to establish or continue in effect generally applicable State business or professional licensing requirements. In general, such requirements would not be "specifically related to hearing products," so they are not subject to section 709(b)(4) of FDARA. If a person purports to be a licensed professional or business, then a State could regulate the person as such. Thus, for example, a person identifying as an "audiologist" would be subject to State professional or facility licensure requirements because an audiologist is a licensed professional.

However, unlike identifying as an "audiologist," some descriptions for professions do not on their own imply licensure in relation to OTC hearing aids. Section 709(b)(4) of FDARA lists certain activities that may be undertaken with respect to OTC hearing aids without the supervision, prescription, or other order, involvement or intervention of a licensed person. FDARA specifically lists the servicing, marketing, sale, dispensing, use, customer support, or distribution of OTC hearing aids. (For convenience, we will refer to these activities collectively as "commercial activity" in this document.) Thus, a person representing as a marketer, seller, dispenser, distributor, or customer support representative (or an equivalent description) of OTC hearing aids would not be a "licensed person" for the purposes of § 800.30 solely for that reason. Nor could a State require such persons to undertake special licensing or equivalent activities. In contrast, a person voluntarily identifying, for example, as a "licensed dispenser" (*i.e.,* not just a "dispenser") would be subject to corresponding State requirements for such dispensers to the extent that the State requirements do not restrict or interfere with commercial activity involving OTC hearing aids (see section 709(b)(4) of FDARA).

The proposed definition of "licensed person" specifies the descriptions of profession, consistent with section 709(b)(4) of FDARA, that would not, on their own, imply licensure relating to OTC hearing aids. Section III.G of this document describes other preemption scenarios in addition to licensed persons.

Defining tools, tests, or software. Another element of the definition of OTC hearing aids requires that users be able to control or customize the devices through tools, tests, or software (see section 520(q)(1)(A)(iii) of the FD&C Act). We interpret this requirement to refer to the ability for a layperson to perform such activities. As such, the proposed definition of "tools, tests, or software" clarifies that OTC hearing aids are those devices that allow lay users to control the device and customize it, such as the device's output, to meet their individual hearing needs.

Other definitions. The proposed definition of "used hearing aid" in both the OTC and prescription device provisions clarifies which hearing aids would be subject to certain proposed labeling requirements for used or rebuilt hearing aids. The proposed definitions are the same for OTC and prescription hearing aids, and they are derived from the current definition in § 801.420 except that we have revised the wording for clarity.

The proposal for prescription hearing aid labeling in § 801.422 retains the definition for "dispenser" that is currently applicable to all hearing aids. However, we propose to revise the wording to clarify that the definition applies only for purposes of prescription hearing aid labeling and propose other clarifying revisions to track the definition of "person" in section 201(e) of the FD&C Act more closely. We believe the definition will continue to be useful because the proposed requirements for prescription hearing aids refer to the dispenser.

FDA welcomes comments on the definitions pertinent to the regulation of OTC hearing aids (as well as any other portion of this proposal). In particular, we seek comments on the clarity of the definitions and ways to improve the definitions to encourage and support the broad availability of safe and effective devices.

C. Labeling (Proposed § 800.30(c))

We are proposing labeling requirements to provide consumers with essential information for the safe and effective use of OTC hearing aids. Section 709(b)(2)(C) of FDARA specifically directs FDA to include, among appropriate labeling requirements, a conspicuous statement that the device is only intended for adults age 18 and older, information on how consumers may report adverse events, information on any contraindications, conditions, or symptoms of medically treatable causes of hearing loss, and advisements to consult promptly with a licensed healthcare practitioner. In addition, section 709(b)(2)(A) of FDARA directs FDA to establish requirements that provide reasonable assurances of the safety and effectiveness of OTC hearing aids, and we intend the proposed labeling requirements to do so.

In considering which statements to require, we note the important role of information in supporting broader use of OTC hearing aids. As part of the 2016 FDA hearing aid workshop, the Hearing Loss Association of America presentation stressed the importance of clear labeling to inform consumers so that the consumer "is empowered and knows what they're buying and knows the limitations and what's possible" (Refs. 9 and 10). FDA agrees, and we have proposed labeling requirements to empower consumers.

Further the proposed conspicuous statement that OTC hearing aids are intended for people age 18 years and older is necessary because the use of OTC hearing aids in people younger than 18 presents risks to health beyond those typically associated with use in older people. Whereas hearing loss in older adults is most commonly related to noise exposure and aging, the etiology (causes) of hearing loss in younger people is varied and may result from conditions that warrant prompt diagnosis to avoid serious risks to health. These conditions may not be readily apparent and can include, but are not limited to:

- Congenital malformations (present since birth) of the external, middle, or inner ear;
- Infections, for example, otitis media (an inflammation of the middle ear) or congenital infections;
- Genetic causes, including hereditary syndromes that can involve cardiac, ophthalmic, renal, neurologic, and other organ systems (that is, syndromes that can involve the heart, eyes, kidneys, nerves, and other organs); or
- Certain exposures, for example, lead poisoning, hyperbilirubinemia (a buildup of a metabolic byproduct, bilirubin, in the blood), and drug ototoxicity (a toxic effect on the ear or its nerves).

The use of a hearing aid to treat hearing loss related to these conditions, without a medical evaluation, may delay diagnosis and treatment of the underlying condition. Further, prompt diagnosis is critical because, left untreated, these conditions may worsen, with potentially lifelong, adverse health effects. Because the use of OTC hearing aids in people younger than 18 presents risks to health beyond those typically associated with use in older people, the proposed conspicuous statements are appropriate and provide reasonable assurance of safety and effectiveness of OTC hearing aids.

The proposed labeling provisions include requirements for labeling on the package and inside the package, along with requirements for labeling on the device itself. These requirements would apply in addition to all other applicable labeling requirements in, for example, parts 801 and 830. In any of the labeling, manufacturers could continue to include additional truthful, non-misleading information provided it does not conflict with other requirements (such as those mentioned above).

In proposing where to place labeling statements—on the package or inside the package—we have considered when users, prospective users, and others should become aware of information (before or after purchase). We have also considered the limited space available on the packaging as well as simplicity of format.

FDA welcomes your comments on the proposed labeling requirements, including the placement or conspicuousness of statements, as well as whether the statements are clear and understandable. For example, in reviewing the proposals, did you find important information quickly? Did you find the information clear and easy to understand? We are particularly interested in your feedback about phrasing or formatting to convey information to people who are anticipated users, or more generally, who are not hearing health professionals. A rationale or evidence would make your feedback more useful. For example, if a proposed statement is unclear, telling us why is generally more helpful than saying only that you find the statement to be unclear.

1. PACKAGE LABELING

We are proposing that the outside of the package include information that consumers would need to know prior to purchasing the device, such as who is a candidate for the device, how to determine if you are a candidate, and when to seek professional help before trying the device. We believe this information empowers consumers and answers threshold questions about the suitability of purchasing an OTC hearing aid for their hearing needs. This proposal would also emphasize who the intended user is, to reduce the likelihood that people younger than 18 would purchase or use an OTC hearing aid.

To summarize, the proposed statements on the package describe:

- A conspicuous warning that the device is not for users younger than 18 years old;
- The symptoms of perceived mild-to-moderate hearing loss;
- Considerations for seeking a consultation with a hearing healthcare professional; and
- Red flag conditions: Warnings to consumers regarding signs and symptoms that should prompt a consultation with a licensed physician (preferably an ear specialist).

However, we are not proposing to require other information on the package, for example, mobile operating system compatibility or whether the package contains the necessary batteries. Further, we are proposing language that accurately conveys information to readers without relying on specialized knowledge (*i.e.,* for laypeople). We welcome your comments on whether to require other information on the package labeling and whether you had any difficulty understanding the information (and if so, your suggestions for improvements).

a. Symptoms suggesting perceived mild to moderate hearing loss. Prospective users may not know their definitive degree, configuration, or etiology of hearing loss. That is, they may not know the exact nature or cause, so commenters for the public meeting discussed various ways to communicate the signs of perceived mild to moderate hearing loss and reasons to seek medical evaluation. They generally agreed that such

information should appear on the outside of the package. We agree with this sentiment and are proposing that the information be readily apparent prior to purchase to help people to determine whether an OTC hearing aid may benefit them.

To that end, we are proposing four scenarios that a person may recognize (symptoms) that suggest perceived mild to moderate hearing loss. We have selected these scenarios because they commonly present difficulties to people with perceived mild to moderate hearing loss and are situations in which users are likely to benefit from the use of OTC hearing aids. We have also based the selection on stakeholder input from the public workshops. Although people with normal hearing may sometimes experience these scenarios, people with perceived mild to moderate hearing loss will experience them more frequently, if not regularly. We have phrased the information to emphasize that the device is intended for people who are 18 or older, and the phrasing avoids medical and technical terms while describing everyday situations.

b. Considerations for seeking consultation with a hearing healthcare professional. However, because a prospective user may have hearing impairment beyond, or different from, perceived mild to moderate hearing loss, we are proposing a statement to assist people in evaluating the potential for increased benefit from an OTC hearing aid. We believe this information is important, and have titled it as such, and appropriate for users and prospective users who are not familiar with hearing aids.

c. "Red flag" conditions. In that vein, we are proposing to continue to require a statement advising users and prospective users to seek medical care if they exhibit any one of a number of conditions. We are not modifying the list of conditions from its present form except for phrasing and formatting changes to improve readability, as well as a change to the time periods (from 90 days to 6 months). We intend the change to the time periods to encourage consumers to consider a longer personal history, which may help them to identify the conditions without the involvement of a licensed person. The list includes reliable indicators of the possibility of an underlying medical condition that a hearing aid cannot treat. For example, fluid, pus, or blood coming out of the ear may indicate an active infection, as could sudden, quickly worsening, or fluctuating hearing loss. An examination by a physician, preferably an ear specialist, would determine whether such an underlying condition is present and treatable, potentially halting or reversing hearing loss.

d. Other information. We are also proposing to require that the outside package include a web address and telephone number for consumers to access a digital copy or request a paper copy of all labeling, including the labeling inside the package, for that OTC hearing aid. A website could provide easy access to the more comprehensive information found in the labeling inside the package and could allow the use of other media to convey information.

FDA is proposing to require that this labeling be available online or be able to be requested by phone prior to purchase to facilitate product familiarity to make a purchasing decision. We believe having the information found inside the package will help prospective users 🗋 choose a safe and effective device without the involvement of a licensed person. As proposed, this information would be available without the need for consumers to register for access, for example, by registering for a website member login.

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Further, a download page could include, but would not be required to include, additional resources, for example, video explanations or tutorials to aid prospective users in selecting and using a device, as well as a mechanism for reporting complaints or adverse events. Since such additional resources would not be required under this proposal, accessing such resources could entail, for example, registering as a website member.

Please note that we are not proposing to require the distribution of paper copies for all OTC hearing aids because an analogous provision in the Hearing Aid Restrictions yielded little benefit—very few people requested a review of the paper copy—while adding to the regulatory burden. We are seeking comment on these proposed requirements (and any other portion of this proposed rule) regarding equitable access to the information and/or OTC hearing aids.

We are also proposing to require that the manufacturer disclose its return policy or, if none, state that it does not accept returns. Such a requirement would be appropriate, because prospective users of OTC hearing aids may be unsure whether an OTC hearing aid will meet their hearing needs. If an OTC hearing aid does not meet a user's hearing needs, the user may leave the device in the "dresser drawer." (This is a common description of the phenomenon of relegating the device to disuse—putting it away, never to use it again—and foregoing the potential benefit of a more-satisfactory device). Thus, a statement of the return policy would be appropriate because, without the services of a licensed person, some users may be more dependent on the manufacturer's return policy (as opposed to the licensed person's) to avoid leaving an OTC hearing aid in the dresser drawer. A statement of the return policy would provide appropriate information to prospective users to help them determine the suitability of options given individual circumstances and preferences such as budget and willingness to try multiple OTC hearing aids. Additionally, consistent with the existing hearing aid requirement in § 801.420(c)(5), we are proposing that, when an OTC hearing aid is used or rebuilt, the outside package declare that fact. These requirements would advance the public health by facilitating the purchase of devices that meet users' hearing needs.

We are not proposing to require that manufacturers accept returns under these proposed Federal regulations. However, we likely would not consider a generally applicable State or local requirement to accept returns (*i.e.,* the requirement applies to any product) as a requirement specifically related to hearing products. Further, we believe that a State or local requirement for retailers (persons who sell to end users) to accept returned OTC hearing aids would likely promote—rather than restrict or interfere with—commercial activity involving the devices by reducing the financial risk to purchasers. As such, generally, State or local requirements for returns would continue to apply provided they do not conflict with the final rule based on this rulemaking. We are seeking comment on whether such a State or local requirement would promote, rather than restrict or interfere with, commercial activities involving OTC hearing aids.

Participants at the June 9, 2017, NASEM public workshop generally agreed with the importance and utility of requiring certain information on the package. Participants discussed potential labeling requirements such as these for OTC hearing aids (see Ref. 11). Numerous participants focused on the signs and symptoms of consumers who have mild-to-moderate hearing loss and might potentially benefit from OTC hearing aids. Specifically, participants expressed concerns that consumers would need information to help decide whether to purchase the products and/or whether to seek professional services. The proposed requirements in this document have taken these comments into account.

2. LABELING INSIDE THE PACKAGE

We are proposing to require that manufacturers place labeling inside of the package with the information that consumers will need after purchasing an OTC hearing aid for its safe and effective use. The proposed content of this labeling includes:

- Warnings, cautions, and notes, including a conspicuous statement warning against the use of the OTC hearing aid in people younger than 18 years old as well as a warning regarding "red flag" medical conditions to prompt consumers to consult with a licensed physician and a note about how to report adverse events to FDA;
- Illustration(s) of and information about the controls, user adjustments, and the battery compartment;
- A description of any accessory that accompanies the OTC hearing aid;

• Adequate directions for use, consistent with § 801.5 (21 CFR 801.5 (/select-citation/2021/10/20/21-CFR-801.5)), including but not limited to information on sizing and inserting the eartip as well as the tools, tests, or software that allow the user to control and customize the OTC hearing aid to the user's hearing needs (*e.g.,* to self-select, self-fit, and self-check the performance of the device);

- Technical specifications to allow users, prospective users, and others to evaluate and compare the performance of OTC hearing aids;
- Description of commonly occurring, avoidable events that could adversely affect or damage the OTC hearing aid;

- Identification of known physiological side effects associated with using the OTC hearing aid that may warrant consultation with a physician, including but not limited to skin irritation and accelerated build-up of ear wax (cerumen accumulation);
- Information on repair services; and
- If clinical or non-clinical studies were conducted by or for the manufacturer to support the performance of the OTC hearing aid, a summary of all such studies.

We believe these labeling requirements for OTC hearing aids will help provide reasonable assurance of safe and effective use of OTC hearing aids for consumers with perceived mild-to-moderate hearing loss. We intend the proposed labeling requirements to provide lay consumers with adequate information, in particular, to ensure that those purchasing OTC hearing aids know when to seek professional intervention, how to use the device safely and effectively, and where and how to obtain additional information or assistance. The 2016 NASEM report supports FDA's proposal in that it similarly recommends that OTC hearing aids "[i]nclude thorough consumer labeling, including information on:

- Frequency gain characteristics;
- adequate directions for use;
- communication challenges for which it may be helpful to seek professional consultation; and
- medical situations, symptoms, or signs for which to consult with a physician" (Ref. 6).

We agree that thorough consumer labeling will assist users, potential users, and others with selecting, fitting, and wearing OTC hearing aids. Even so, the proposed requirements in this rulemaking are not intended as a substitute for other FDA regulations. Thus, for example, if adequate directions for use were to require additional information beyond that proposed in this rulemaking, manufacturers would need to include that additional information (see § 801.5 regarding adequate directions for use).

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As for the NASEM report's recommendations for OTC hearing aids regarding information about communication challenges and medical indicators, we agree that such information will help provide reasonable assurance of safety and effectiveness, and we have included that information, as well as the full-on gain value in our proposed labeling requirements. (Gain is a measure of amplification, and its full-on value is its maximum. We provide an explanation of gain in section III.D.2.)

We are not proposing to require additional technical information in the labeling for OTC hearing aids other than those in proposed § 800.30(c)(4); however, the labeling may optionally include such information if desirable. For example, technical information similar to what is currently required for all hearing aids may be useful in assisting audiologists offering services to users (see § 801.420(c)(4)). Multiple stakeholders voiced a similar view during the 2016 FDA workshop (Refs. 9, 10, and 12). Some added that scientific or technical information (in addition to the information we are proposing to require for OTC hearing aids) may be meaningful for consumers to make their decisions, especially if they are familiar with the technology. Although such additional information may be desirable for some consumers, FDA does not believe it is necessary to assist consumers in their selection.

FDA intends to issue at a later date a separate comprehensive guidance document that discusses, in part, labeling information and communicating that information with the goals of increasing transparency and choice to consumers. In accordance with 21 CFR 10.115 (/select-citation/2021/10/20/21-CFR-10.115), we will announce the availability of the draft of that guidance separately from this rulemaking, and the announcement will include information for submitting comments about that guidance, which will be separate and distinct from comments for this rulemaking. We do not intend to consider comments submitted to the docket for this rulemaking unless they pertain to the proposals in this document.

3. LABELING ON THE DEVICE ITSELF

We are proposing to require that the labeling on the device itself include the serial number and symbol(s) for proper battery insertion orientation when applicable. If the device has been used or rebuilt, a tag indicating such would have to be physically attached to the device in addition to the statement on the outside of the package.

D. Output Limits (Proposed § 800.30(d))

FDA is proposing a maximum acoustic output limit requirement for an OTC hearing aid to provide reasonable assurance of safety and effectiveness. Section 709(b)(2)(B) of FDARA directs FDA to establish or adopt output limits appropriate for OTC hearing aids. A high output can be unsafe and further impair hearing. However, too low an output reduces device effectiveness and can lead to poor device performance, including clipping and distortion. In turn, poor performance would reduce consumer satisfaction and use of the devices. We believe that the proposed output limits balance the above considerations for these devices, so the limits are therefore appropriate for OTC hearing aids.

1. OVERVIEW OF PROPOSED OUTPUT LIMITS

We propose a maximum OSPL90 output level of 115 dB sound pressure level (SPL) as a general rule to balance consumer safety with device performance.[7] However, we would permit a limit of 120 dB SPL for an OTC hearing aid that implements input-controlled compression and a user-adjustable device volume control (*i.e.,* volume adjustment). This is because a user-adjustable volume control allows the user to reduce the output below the maximum, in effect, further reducing the device's limit. Input-controlled compression is an automatic function that dynamically reduces the output of frequency ranges based on the input. Both of these design features thus reduce the likelihood that a user will experience high acoustic outputs, at the device's limit, at any given moment. Relatedly, we are proposing that the device labeling state the value of the maximum OSPL90 level (see section III.C.1).

We have proposed output limits to prevent injuries from exposure to loud sounds when amplified by OTC hearing aids while still allowing a sufficient dynamic range of outputs, called “headroom,” to provide effective amplification for users with perceived mild to moderate hearing loss. A device without sufficient headroom (when the output limit is too low) would not be as effective as a device with a higher output. However, a device with too high an output limit could further worsen hearing impairment.

2. DATA AND STAKEHOLDER PERSPECTIVES ON THE PROPOSED OUTPUT LIMIT

We base the proposed limits on physiological data and stakeholder input, some of which appear in Clause 4.3 of ANSI/CTA-2051, a voluntary consensus standard (Ref. 13). Note that, although ANSI/CTA-2051 is a consensus standard for PSAPs, we believe that this standard is also relevant for OTC hearing aids, which provide personal sound amplification, albeit for purposes of aiding with or compensating for impaired hearing. The standard's basis for the output limit is a national workplace safety guideline, *Occupational Noise Exposure,* from the National Institute for Occupational Safety and Health (NIOSH) (Ref. 14). NIOSH developed this standard, which we will refer to as NIOSH-98, to define permissible exposure time depending on the intensity of the sound.

In general, the relationship between the loudness (SPL) and the time before damage to hearing is inversely related: The louder the sound, the shorter the time before hearing damage. Above about 85 dBA (A-weighted decibels), the exposure time is cut in half for every 3 dB increase in sound level (Ref. 14).[8] Thus, the difference between recommended exposure times for 115 dB SPL and 120 dB SPL is approximately 61 seconds, where 115 dB SPL provides approximately triple the permissible exposure time than 120 dB SPL (see the next section for a more detailed explanation of the “3-dB exchange rate”).

Appendix A of ANSI/CTA-2051 describes this tradeoff between output level and exposure time, providing a rationale for a maximum OSPL90 output limit of 120 dB based on NIOSH-98. For the purposes of that standard, NIOSH found that 115 dBA SPL is acceptable for up to about 30 seconds. ANSI/CTA-2051 explains that this allows the user sufficient time to turn off or remove the hearing aid before the exposure becomes unacceptably dangerous to hearing ability. ANSI/CTA-2051 observes that sound levels of desirable, “real-life

sonic events" can approach the NIOSH-98 level, for example, a live symphony in which a user would want to experience "occasional peaks" undistorted. However, a lower output limit would not allow enough headroom for a faithful reproduction of such peaks and would lead to output clipping or distortion. Thus, a limit that allows desirable peaks, but sufficient time to react to undesirably loud sounds, would be ideal. As ANSI/CTA-2051 explains, 115 dBA is equivalent to an OSPL90 value of approximately 120 dB SPL with an allowance of 28 seconds to react.

FDA agrees that an OTC hearing aid should provide sufficient headroom to amplify relatively loud sounds such as those in a symphony, yet the device should not have an output so high that the user does not have time to act before sustaining injury. Further, the output should not be consistently at a limit of 120 dB SPL, accomplished through the inclusion of input-controlled compression and user-adjustable volume control.

In addition to considering the ANSI/CTA and NIOSH standards supporting the proposed limits, we considered stakeholder input. On June 9, 2017, NASEM held a public workshop meeting where participants discussed, among other topics, a 120-dB SPL maximum output limit for an OTC hearing aid (see Ref. 11). Numerous speakers commented that an OSPL90 output limit somewhat lower than 120 dB SPL for OTC devices would likely still provide sufficient amplification and headroom for individuals with perceived mild to moderate hearing loss while providing a safety margin in terms of sound-intensity exposure.

Additional comments during the NASEM workshop raised the importance of input-controlled compression and the inclusion of a user-adjustable volume control in order to help reduce overamplification. Each of those features can limit the device's output by dynamically reducing device gain as the input level increases, thus increasing the safety profile of a device: The user generally would not be listening at louder output levels as often as would occur without these features.

FDA has also reviewed numerous public comments on the risk of harm from excessive output, stemming from our 2016 public workshop, Streamlining Good Manufacturing Practices (GMPs) for Hearing Aids (see Refs. 9, 15, and 16). We agree that excessive amplification from OTC hearing aids could pose a risk to individuals' health and thus are proposing that the maximum output (OSPL90) of OTC hearing aids not exceed a certain value, depending on device design features, that would provide users enough time to react to loud sounds to prevent injuries.

Some stakeholders have suggested inclusion of gain limits for OTC hearing aids. Gain is a measurement based on the ratio between the output and the input or, to simplify further, how much the device amplifies (or reduces) the input. A gain limit would further reduce the maximum device output because the device would sometimes reach the gain limit, providing no further amplification, before it reached the output limit. We are proposing not to limit the device gain because we believe that the proposed maximum output limit (together with the other proposed requirements) will provide reasonable assurance of safety and effectiveness without limiting the device gain also.

Moreover, a gain limit may unduly constrain the design of effective devices. Appropriate gain characteristics can depend on the implementation of the amplification circuit design (*e.g.,* linear amplification versus wide dynamic range compression). Thus, appropriate gain settings for one device may not be appropriate for another device of a different design. We believe that allowing flexibility in the gain settings will help maximize the effectiveness of the particular circuit design a manufacturer implements for a device to address perceived mild to moderate hearing loss. In light of this, and since a maximum output limit would also in effect limit gain, we do not believe a separate, additional gain limit is necessary to provide reasonable assurance of safety and effectiveness. We also note that the NASEM report does not recommend any limit on gain for OTC devices, only on maximum output (Ref. 6).

3. THE PROPOSED OUTPUT LIMIT REQUIREMENTS HELP PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS

In further consideration of user-adjustable volume controls and input-controlled compression, we believe that these two design features together will sufficiently mitigate the risk of a higher maximum output limit (from 115 dB SPL up to and including 120 dB SPL) by reducing the likelihood that the user will experience excessive sound levels for periods long enough to sustain damage to hearing (Ref. 14). Input-controlled compression such as wide dynamic range compression is also associated with hearing performance benefits in realistic environments that have varying levels of sound intensity for persons with mild-to-moderate sensorineural hearing loss (see, *e.g.,* Refs. 17 to 21). That is, besides reducing the device's effective output limit, input-controlled compression also generally helps users hear better in daily situations.

In reaching this proposal on output limits, we note that hearing aids, including OTC hearing aids, are intended to be worn during all waking hours in a wide variety of listening environments and situations. Thus, user comfort is relevant to safety and effectiveness, and input-controlled compression and user-adjustable volume control increase comfort by dynamically adjusting gain and keeping outputs lower. This contributes to effectiveness and user satisfaction because users are generally more willing to wear a comfortable device consistently, maximizing the benefits of the device and the impact on public health.

We are not proposing to require input-controlled compression and a user-adjustable volume control for all OTC hearing aids, however. Thus, devices that do not have both of these features (which, in effect, reduce the device's output limit) would have to respect a 115 dB SPL limit, which would more than triple the safe exposure time compared to a 120 dB SPL limit (Ref. 14).[9] Users would have ample time to take appropriate action to mitigate unacceptably high sound levels, for example, by adjusting the volume (if the device has a user-adjustable volume control), turning the device off, removing the device from the ear, or moving out of the loud environment. As noted above, the device labeling would also be required to include a reminder to consumers that, if they are in a loud listening environment that warrants hearing protection, they should remove their hearing aid(s) and use hearing protection.

To summarize, we believe that a 115 dB SPL output limit would help provide reasonable assurance of safety and effectiveness for the intended population. However, we acknowledge that 120 dB SPL could have additional effectiveness potential in certain circumstances, for example, when listening to a symphony by a live orchestra (Ref. 13). As discussed above, we believe that achieving that potential would be safe only if the device also includes input-controlled compression and a user-adjustable volume control. Overall, we believe this device-design contingent proposal for output limits helps provide reasonable assurance of safety and effectiveness of OTC hearing aids while providing ample design space for innovation.

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E. Other Requirements (Proposed § 800.30(e) and (f))

Although certain labeling and output limits are necessary for reasonable assurance of safety and effectiveness of OTC hearing aids, these requirements alone are not sufficient to do so. FDA is therefore proposing that the devices must meet certain performance and design requirements in order to help provide reasonable assurance of safety and effectiveness, pursuant to section 709(b)(2)(A) of FDARA.

1. ELECTROACOUSTIC PERFORMANCE REQUIREMENTS TO HELP PROVIDE A REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS

We are proposing to establish electroacoustic performance requirements to help ensure that the output of an OTC hearing aid safely and effectively compensates for perceived mild to moderate hearing loss in people age 18 and older. Electroacoustic performance describes how well a hearing aid converts an electrical signal, either digital or analog, into a sound (acoustic energy) or vice versa. Currently, hearing aid labeling must include technical data for certain performance characteristics gathered according to the test methods specified in ANSI/ASA S3.22-2003 (see § 801.420(c)(4)). We do not believe, however, that the data that conform to ANSI/ASA S3.22 are adequate for consumers to select their own hearing aid without the supervision, involvement, or intervention of a licensed person (among other reservations).

This is because ANSI/ASA S3.22 does not specify any minimum performance requirements. Instead, it specifies tolerances, which are acceptable ranges of deviation from manufacturer-stated specifications. The manufacturer, not a standard, determines how the hearing aid performs. As a result, achieving optimal hearing aid performance currently depends in part on interpreting the technical data supplied by the manufacturer for selection and adjustment. The interpretation of this information is highly technical, so the information is useful to a professional but generally not the lay user.

For OTC hearing aids, we believe that the devices must meet certain electroacoustic performance specifications so that any OTC hearing aid would perform safely and effectively for perceived mild to moderate hearing loss after the user customizes the device for individual needs. To that end, we are proposing to use several applicable specifications for device performance from ANSI/CTA-2051 for OTC hearing aids. A device that met these performance specifications would safely and effectively reproduce sounds without the need for professional involvement.

Specifically, an OTC hearing aid should provide amplification with high fidelity so that the user can accurately perceive daily social and environmental sounds. High-fidelity (accurate) output means that the device reproduces the input frequencies clearly, without distortion and without undue frequency shaping. We believe such an OTC hearing aid will have certain performance characteristics to achieve fidelity: The OTC hearing aid would have sufficiently low distortion, would not introduce excessive self-generated noise or time delays between input and output, and would provide a sufficient frequency response bandwidth and smoothness. An OTC hearing aid would have to achieve these, after customization to the individual's hearing needs, without the intervention of a licensed professional; that is, by design.

We have reviewed ANSI/CTA-2051:2017, which includes specifications for electroacoustic performance, and we believe that performance requirements based primarily on its Category 1 specifications would help provide reasonable assurance of safety and effectiveness of OTC hearing aids.[10] These specifications relate to the device's processing of the input sound (the sounds detected by the device) to generate the output sound (the amplified sound that the device produces to assist the user). To summarize, FDA believes that the specifications that would help provide reasonable assurance of safety and effectiveness, as well as set an objective baseline for device performance, are:

- Distortion control limits;
- Self-generated noise limits;
- Latency limit;
- Frequency response bandwidth; and
- Frequency response smoothness limits.

We believe that the above listed electroacoustic requirements would ensure that an OTC hearing aid can accurately reproduce daily speech and other environmental sounds without the need for professional involvement. We believe that this performance level is requisite for the device to meet the needs of people with perceived mild to moderate hearing loss. Likewise, the performance requirements would help ensure that undesirable effects (such as distortion) do not impair safety and effectiveness.

ANSI/CTA-2051 is, to FDA's knowledge, the first voluntary consensus standard to describe performance characteristics for hearing amplifiers (as opposed to standardized test methods and tolerances). Upon reviewing the voluntary consensus standard, and in consideration of related presentations during FDA's 2016 hearing aid workshop, we believe that the rationale and methodology of the standard are sound, and we believe that adhering to the specifications in this standard would yield high-fidelity OTC hearing aids. However, we are proposing to establish as requirements the subset of those specifications that we believe would help provide reasonable assurance of safety and effectiveness in conjunction with the other proposals in this rulemaking.

Whether to require such electroacoustic performance specifications for OTC hearing aids, and the specific values, were topics of discussion during the June 9, 2017, NASEM public workshop (Ref. 11). Additionally, public presentations of amplification measurements at FDA's hearing aid workshop showed performance differences and suitability in terms of frequency response bandwidth and smoothness across devices that presenters considered (Refs. 9, 15, 16, 22). After seeing such information, several participants opined that the Category 1 limits of ANSI/CTA-2051, together with the device latency limits (a Category 2 limit in ANSI/CTA-2051), would collectively help ensure safety and effectiveness of an OTC hearing aid with respect to its electroacoustic performance.

In addition to the performance aspects of the voluntary consensus standard, we recognize that aligning FDA regulations with a voluntary consensus standard may reduce administrative burdens while encouraging and facilitating greater availability of safe and effective OTC hearing aids. Note that we are not proposing to apply the electroacoustic performance requirements to prescription hearing aids, nor are we proposing to establish requirements for OTC hearing aids that mirror the technical data requirements under current § 801.420(c)(4). We expect that the involvement of a licensed professional for prescription hearing aids will help provide for reasonable assurance of safety and effectiveness for those devices. Similarly, although the technical data in current § 801.420(c)(4) will assist licensed professionals to select and fit a prescription hearing aid, we do not believe that the technical data are generally helpful for lay users of OTC hearing aids that meet electroacoustic performance requirements.

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a. Distortion control limits. Distortion control limits describe how faithfully an OTC hearing aid reproduces a given frequency or range of frequencies at a given sound pressure level. An OTC hearing aid that produces less perceptible total harmonic distortion, plus hearing-aid-originated noise (*i.e.,* total harmonic distortion plus noise), will deliver a higher-fidelity sound to the user, meaning that the user will be able to perceive sounds more accurately or clearly than a device with higher perceptible total harmonic distortion plus noise. Total harmonic distortion plus noise can depend on both the input and output sound pressure levels and the corresponding (level-dependent) gain settings of the device if applicable. We believe that the proposed allowable levels of total harmonic distortion plus noise, when measured as proposed at the specified sound pressure levels, will help ensure accurate or clear amplification for the user of an OTC hearing aid.

b. Self-generated noise level limit. The self-generated noise level limit describes the maximum sound pressure level of noise that the OTC hearing aid may produce, where “self-generated noise” means sounds that are present in the output but not the input. Excessive self-generated noise can obscure or overwhelm softer output sounds, preventing the user from hearing such sounds. Excessive self-generated noise may also distract or annoy users. Appropriately limiting self-generated noise will therefore help users to hear softer output sounds as well as improve their experience by avoiding the production of perceptible noise or sounds that are not input sounds. We believe that the proposed rule will appropriately limit self-generated noise.

c. Latency limit. The latency limit describes how quickly an OTC hearing aid produces the output sound relative to the input sound. A shorter latency interval means that the device takes less time to produce the output, and when short enough, the user will not perceive a delay. A perceived delay is generally most noticeable when the device amplifies the user's own voice, causing an effect much like an echo that can be disorienting, distracting, or annoying. We believe that the proposed latency limit will help to avoid perceptible output delays that would reduce the benefit from an OTC hearing aid.

d. Frequency response bandwidth. The frequency response bandwidth of an OTC hearing aid is the range of frequencies that the device can reproduce for the user to hear. Cutoff frequencies, both lower and upper, are the limits of the bandwidth. The device would generally not sufficiently amplify signals with frequencies outside of these limits, meaning, below the lower cutoff or above the upper cutoff. A wider bandwidth means that the device can amplify a broader range of sound frequencies for users to hear. A bandwidth that is too narrow, especially if the upper cutoff is too low, will result in insufficient amplification of critical high-frequency sounds, including but not limited to speech sounds such as /s/,/z/,/t/, and/sh/. We believe that

the proposed required frequency bandwidth, 250 Hz to 5 kHz, will ensure amplification of daily speech or other environmental sounds because almost all such sounds typically fall between these proposed lower and upper cutoff frequencies.

e. Frequency response smoothness limit. The frequency response smoothness limit describes how uniformly the OTC hearing aid amplifies different frequencies over its bandwidth. A uniform frequency response when graphed would correspond to a smooth and relatively uniform curve, which is the "smoothness" described by this limit. To describe this requirement, we divide the frequency range into multiple, narrower ranges called one-third octave bands. Any given peak in a one-third octave band would have to remain below a set level compared to neighboring bands, two bands above and two bands below, based on the averages. Meeting this requirement for frequency response smoothness means that the amplification performance is consistent across frequencies for users.

If a device does not amplify sounds uniformly across frequencies, the user would potentially perceive differences in intensity for different frequencies, reducing the audio fidelity and consequently the user's hearing perception. This may include a perceptibly altered speech quality (such as undue changes in the tone or timbre of the intended sound), which may be distracting or annoying. In addition, device output that is relatively excessive at lower frequencies (compared to higher frequencies) poses an increased risk for damaging a user's hearing at lower frequencies. This is because the typical user has more residual hearing (*i.e.,* better hearing thresholds) at lower frequencies, consistent with a typical sloping hearing loss, the kind of hearing loss associated with aging. We believe that the proposed frequency response smoothness limit will ensure consistent performance across frequency ranges and thereby help to provide reasonable assurance of device safety and effectiveness.

f. Performance test methods. For each of these proposed electroacoustic requirements, we are specifying performance test methods, including input and output sound pressure levels when appropriate. We are proposing specific performance test methods because different test methods could yield different results for the same metric of device performance. Thus, specifying test methods helps establish a common baseline to benchmark performance for any given device. Additionally, a common baseline would allow prospective users and others to compare electroacoustic performance across devices. Facilitating comparison shopping may also promote users' satisfaction with the OTC hearing aids that they decide to purchase.

2. DESIGN REQUIREMENTS TO ENSURE PROPER PHYSICAL FIT AND PREVENT USER INJURY

We are proposing that the design of an OTC hearing aid must meet certain requirements for safety and effectiveness:

- Maximum insertion depth;
- Eartip made from atraumatic materials;
- Proper physical fit; and
- Tools, tests, or software allowing the lay user to control the device and customize it to the user's hearing needs.

The above listed requirements seek to balance effective fit and safe fit of an OTC hearing aid, accomplished by users themselves, without professional assistance. An OTC hearing aid eartip (the part of the OTC hearing aid that contacts and fits into the user's ear) must fit the user so the device performs optimally, but an OTC hearing aid must not damage the ear, including the ear canal and eardrum (tympanic membrane).

The device could damage the ear by scratching (abrading) the skin around the eartip parts, puncturing the eardrum, or exacerbating hearing loss if the device is too close to the eardrum. In particular, the skin that lines the ear canal is especially thin and delicate. The lateral (outer) third of the canal is composed of cartilage, and the medial (inner) two-thirds, which ends at the ear drum, of bone. Each of these parts of the ear is therefore quite sensitive and easily injured. To provide reasonable assurance of safety and effectiveness, the design of an OTC hearing aid must allow insertion and prolonged contact with these

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sensitive areas while preventing injury to them. We believe the above listed requirements would ensure proper physical fit for optimal performance while avoiding injury to the user's ear canal skin, bony inner ear canal, the eardrum, or other middle ear structures.

a. Maximum insertion depth. We considered whether we could express a design requirement for manufacturers for maximum insertion depth as a given length. However, specific anatomical dimensions such as the length of the cartilaginous and bony portions of the external auditory canal and distance to the tympanic membrane can vary greatly among adults. That is, the distance to the eardrum differs greatly from person to person. A given length may be too long for one person (potentially resulting in injury with device insertion or placement) but too short for another (potentially impairing device performance by too shallow of an insertion). In contrast, we believe that the bony-cartilaginous junction is a readily identifiable and consistent anatomical landmark that can serve as a design limit for manufacturers of OTC hearing aids. That is, we believe a practical way to describe the depth limit is to base it on the area of the ear canal corresponding to where cartilage meets bone. However, we welcome comments, particularly those with support from peer-reviewed sources, about other design requirements (*e.g.,* in terms of absolute length) to limit the insertion depth and prevent damage to the tympanic membrane or other injuries while also promoting device effectiveness.

b. Construction from atraumatic materials. We are proposing that the eartip be encased by atraumatic materials, that is, materials that prevent injuries to the skin and bone, for example, because they are very flexible. The use of atraumatic materials reduces the chance that daily use or accidental contacts will cause damage to the delicate skin or bone of the ear.

c. Proper physical fit. We are proposing that the OTC hearing aid have features that enable users to readily achieve a safe, customized, acoustically favorable, and comfortable physical fit in the ear canal and/or external ear. For example, the manufacturer may wish to provide interchangeable eartips of varying sizes. However, we are not proposing a specific design feature or strategy because such specificity may constrain the design of an OTC hearing aid and impede design innovations. This proposed requirement corresponds with the proposed labeling requirements to describe how users may obtain such a fit, including sizing or inserting the eartip to minimize the risk of injury.

d. Tools, tests, or software. We are proposing to codify the requirement that an OTC hearing aid must include tools, tests, or software through which a lay user can control the device and customize it to the user's hearing needs. Examples of tools, tests, or software include but are not limited to: A user-adjustable volume control, a user-adjustable tone control, the ability for a user to change preset listening programs manually, interactive software for self-selecting, testing, and fitting, or a switch to enable or disable automatically determined settings, such as acoustic environment sensing or noise cancellation. An OTC hearing aid would need to include tools, tests, or software, or some combination of those features, sufficient to customize the device to meet the user's hearing needs.

3. QS REQUIREMENTS

We are soliciting further input on potential revisions to the applicable QS requirements for OTC hearing aids. The input that we have already received, while valuable, is sometimes contradictory and does not fully address FDA's concerns for the quality of medical devices. As described in section I.C, we received stakeholder input suggesting that FDA reduce the provisions of the QS regulation applicable to the devices as the provisions are overly burdensome. We also received input that the current requirements are important and not unduly burdensome (Ref. 9). While FDA wishes to minimize regulatory burdens, we must have reasonable assurance of safety and effectiveness, which a quality system helps to provide.

In considering the range of feedback already received, we note that the QS requirements are interdependent yet inherently flexible. This scheme relies on each of the provisions working together. Further, because hearing aids are medical devices, a quality system for medical devices specifically, as opposed to a quality

system for consumer electronics more generally, is necessary to provide reasonable assurance of safety and effectiveness. This is because medical device quality systems address regulatory concerns regarding safety and effectiveness that systems for consumer electronics do not.

While the use of the quality system described in part 820 would be more appropriate for OTC hearing aids and straightforward to implement than another standard with various reservations, exceptions, and modifications, FDA is open to considering alternatives to the existing QS requirements. Any such changes would be proposed in a separate rulemaking proceeding, and interested parties would have an opportunity to comment during that rulemaking. However, we welcome proposals for how the QS requirements could be modified, or an alternate approach implemented, to ensure the quality of OTC hearing aids and provide a reasonable assurance of safety and effectiveness.

Finally, with regard to the QS requirements, FDA is undertaking other separate efforts to minimize regulatory burdens for manufacturers by proposing the harmonization of part 820 with an international consensus standard.

In light of the foregoing—including contradictory input already received, the inherent flexibility of the QS requirements, the need for a quality system suited to medical devices, and other changes that FDA is proposing—we are seeking further input on potential modifications to the QS requirements that would be applicable to OTC hearing aids to inform future rulemaking.

F. Condition for Sale (Proposed § 800.30(g))

FDA is proposing to establish a condition for sale of OTC hearing aids to prevent sale to people younger than 18, helping to provide reasonable assurance of safety and effectiveness. We are proposing the condition for sale pursuant to section 709(b)(2)(D) of FDARA, which directs FDA to describe the requirements under which the sale of OTC hearing aids is permitted, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online. For the purposes of this provision, we interpret "sale" broadly to include, among other transactions, leases and rentals.

The proposed condition for sale is consistent with 709(b)(2)(C) of FDARA and section 520(q)(1)(A)(ii) of the FD&C Act, which establish that OTC hearing aids are only intended for people age 18 and older. As described above, the use of OTC hearing aids in people younger than 18 presents risks to health beyond those typically associated with use in older people. Accordingly, we are proposing to prohibit the sale of an OTC hearing aid to or for a person younger than 18 years.

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FDA has considered whether other conditions for sale for OTC hearing aids are necessary in addition to the proposed labeling that includes conspicuous statements that OTC hearing aids are only intended for people age 18 and older. This proposed condition for sale provides a basis for comments on the subject.

FDA also considered whether requirements on sellers to verify the age of purchasers or, in the case of online or mail-order sales, the age of the recipient, would promote the public health. However, mindful that the current conditions for sale have been criticized as described above, we believe that a requirement to obtain proof of age could make hearing aids more difficult to obtain. For example, people with limited means or mobility may not have a government-issued photographic identification that shows their birthdate. Similarly, age verification for online or mail-order sales could impede delivery of OTC hearing aids or reduce the number of willing sellers, which could disproportionately affect OTC hearing aid access in remote or rural areas. Moreover, FDA does not expect high demand for OTC hearing aids from or for people younger than 18. Thus, a requirement for age verification could impose a barrier to access, particularly for underserved populations, without a corresponding benefit to the public health.

FDA welcomes your comments on whether a prohibition of sales to or for people younger than 18 years, without the need to verify age, would best promote access to OTC hearing aids while protecting the hearing health of people younger than 18 years. Alternatively, we welcome your comments on what other conditions for sale may protect the hearing health of people younger than 18 years. In the case of alternative conditions for sale, FDA is particularly interested in conditions that would not disproportionately burden underserved communities. FDA is also interested in your comments on whether labeling, without the prohibition on sales, adequately protects the health of people younger than 18.

We intend to minimize burdens and provide flexibility for sellers, while also protecting the hearing health of people younger than 18, helping to promote the public health by promoting the availability of OTC hearing aids for people who are 18 and older.

G. Preemption Provisions (Proposed § 800.30(h))

FDA is proposing to codify the provisions regarding preemption and private remedies under section 709(b)(4) and (5) of FDARA to assist stakeholders in understanding the legal framework for OTC hearing aids. These provisions are not codified in the FD&C Act, meaning they do not appear under Title 21 of the U.S. Code, but apply nonetheless. We believe that including these provisions in the Code of Federal Regulations will assist our stakeholders, who may not be as familiar with requirements that are not codified in the FD&C Act, such as these, by consolidating applicable requirements in one location that is more familiar.

This may be particularly helpful because FDARA added to the existing preemption framework for devices. In general, under section 521(a) of the FD&C Act, device requirements established by a State (or a political subdivision) are preempted when the requirements are different from, or in addition to, requirements applicable to the device under the FD&C Act and which relate to the safety or effectiveness of the device or to any other matter included in the requirements applicable to the device. FDA may by regulation grant or deny exemptions to this preemption in response to an application from a State (or political subdivision) under certain conditions specified in section 521(b) of the FD&C Act. Prior to the enactment of FDARA, FDA issued regulations in response to such applications, most of them relating to hearing aids, which are codified in part 808.

However, section 709(b)(4) of FDARA established preemption specific to OTC hearing aids that is different from the general rule for preemption under section 521(a) of the FD&C Act. Although FDARA did not explicitly address the existing exemptions from preemption related to hearing aids, section 709(b)(4) of FDARA applies preemption to any requirement of a State (or local government) specifically related to hearing products, that would restrict or interfere with commercial activity involving OTC hearing aids (which, as mentioned above, we will use as shorthand in this document for the servicing, marketing, sale, dispensing, use, customer support, or distribution of OTC hearing aids through in-person transactions, by mail, or online), that is different from, in addition to, or otherwise not identical to, FDA's regulations issued under FDARA section 709(b). We are therefore proposing to amend the scope of part 808 to reflect the additional preemption set by FDARA (see section III.I.1).

1. FDARA PREEMPTS STATE REGULATION OF OTC HEARING AIDS

Under FDARA section 709(b)(4), the OTC Hearing Aid Controls that are the subject of this rulemaking, proposed § 800.30, if finalized, would preempt any State or local requirement specifically related to hearing products that would restrict or interfere with commercial activity involving OTC hearing aids, that is different from, in addition to, or otherwise not identical to, the OTC Hearing Aid Controls, including any State or local requirement for the supervision, prescription, or other order, involvement, or intervention of a licensed person for consumers to access OTC hearing aids.

FDA interprets section 709(b)(4) of FDARA, including the terms therein, as consistent with its purpose that State or local government requirements specifically related to hearing products not restrict or interfere with commercial activity involving OTC hearing aids. For example, we interpret this provision as preempting State or local requirements specifically related to hearing products that would restrict or interfere with

leases, consignments, or deliveries of OTC hearing aids, though not explicitly mentioned in FDARA, because such activities fall within the commercial activity involving OTC hearing aids covered by the provision, in this example, within the marketing, sale, dispensing, use, and/or distribution. Further, the FDARA preemption provision applies to requirements specifically related to hearing products generally, as opposed to devices or hearing aids more specifically, where such requirements restrict or interfere with commercial activity involving OTC hearing aids.

As explained, we do not interpret section 709(b) of FDARA as necessarily preempting State requirements regulating professional services such as speech pathology, audiology, or fitting. A State could, for example, continue to regulate such professional services generally. However, to the extent State or local governments require that purchasers of OTC hearing aids seek those services, such requirements would be preempted by section 709(b)(4) of FDARA as interfering with or restricting commercial activity involving OTC hearing aids. The same would be true were a State, for example, to require providers to undertake an activity, such as certification and examination specific to hearing aids, in order to sell OTC hearing aids.

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2. GENERALLY APPLICABLE STATE AND LOCAL REQUIREMENTS ARE NOT NECESSARILY PREEMPTED UNDER FDARA

As noted in section III.B, FDA does not interpret FDARA to preempt generally applicable requirements. By "generally applicable," we mean that the requirement relates to other products in addition to hearing products, to services not specific to hearing products, or to unfair trade practices in which the requirements are not limited to hearing products.[11] Requirements that apply to any place of business that offers goods or services for sale would likely be generally applicable and therefore not preempted (see also § 808.1(d)(1)). Similarly, requirements that apply to certain places of business may be generally applicable provided the requirements do not attach on account of selling, or other commercial activity involving, hearing products. State or local requirements that make compliance with Federal regulations enforceable by State or local authorities would also not generally be preempted. The examples below focus only on the FDARA preemption provision that applies to OTC hearing aids.

a. Example 1. For example, any given pharmacy may be subject to certain State licensing requirements that apply regardless of whether the pharmacy sells OTC hearing aids; it would not be exempt from such licensing requirements merely because it sells OTC hearing aids. Similarly, a requirement to include terms of sale or return on the receipt that applied also to the sales of other (non-hearing) products would not be preempted.

b. Example 2. In contrast, requirements that attach on account of the sale of hearing products (or would not attach but for the sale of hearing products), would not be "generally applicable." For example, a requirement that any place of business must obtain a license or certification to sell OTC hearing aids would be a requirement specifically related to hearing products. In addition, it would serve to restrict or interfere with commercial activity involving OTC hearing aids and would be different from, in addition to, or not otherwise identical to, the regulations issued under section 709(b) of FDARA. Therefore, it would be preempted.

A requirement may attach on account of the sale of hearing products in a more indirect manner as well, and if it was in effect different from, in addition to, or not otherwise identical to the terms of the statute or Federal regulations, and if it restricted or interfered with commercial activity involving OTC hearing aids, it would be preempted. That is, a State or local requirement may appear on its face to be generally applicable, but if in practice it was specifically related to hearing products and would restrict or interfere with commercial activity involving OTC hearing aids, the State or local requirement would be preempted.

c. Example 3. A requirement that a retailer may only sell OTC hearing aids when it has an audiologist on premises would require the involvement of a licensed person in at least some cases. This requirement would restrict or interfere with commercial activity involving OTC hearing aids, including by requiring the involvement of a licensed person, and would be preempted.

d. Example 4. Similarly, a requirement that sellers advise purchasers of any hearing aids, whether prescription or OTC, of specific medical information not required in the OTC Hearing Aid Controls would be preempted with respect to the sale of OTC hearing aids. Although the requirement attaches on account of the sale of hearing aids more generally (not just OTC devices), it is "specifically related to hearing products" and would operate as a condition of sale that is different from, in addition to, or otherwise not identical to those proposed in this rulemaking. The requirement would also restrict or interfere with commercial activity involving OTC hearing aids. Therefore, the requirement would be preempted as applied to the sale of OTC hearing aids.

e. Example 5. A professional or ethical requirement that deemed a sale to be professional malpractice if the dispenser permitted the sale of any hearing aid without consultation would be preempted under FDARA. It specifically relates to hearing products and by requiring consultation prior to the sale of an OTC hearing aid, it would restrict or interfere with commercial activity involving OTC hearing aids even though the requirement on its face applies only to the dispenser (who must meet licensing requirements).

f. Example 6. A requirement that a seller maintain a statement of medical examination, in connection with the sale of a hearing product, would be preempted under FDARA because such a condition of sale would restrict or interfere with commercial activity involving an OTC hearing aid. Moreover, the requirement for a statement of medical evaluation would restrict or interfere with commercial activity involving OTC hearing aids by requiring the involvement of a licensed person during the course of the commercial activity.

3. REQUIREMENTS FOR PROFESSIONALS AND ESTABLISHMENTS

As with generally applicable requirements, we do not interpret section 709 of FDARA as generally prohibiting the regulation of professionals or establishments or exempting them from applicable professional requirements, even in the case that the professional or establishment only undertakes activities related to OTC hearing aids. Thus, a person that purports to be a specially licensed professional or establishment would be subject to applicable State and local requirements. Such requirements may include periodic professional examination or mandating the availability of testing equipment.

FDA does, however, interpret section 709 of FDARA as preempting certain kinds of professional or establishment requirements. To use one specific example, many States have established definitions for hearing aid fitters, dispensers, or other sellers and servicers. In some cases, State or local requirements may deem an individual or establishment to be a dispenser (or other defined term) by virtue of engaging in the sale of or providing services for hearing aids. That status in turn incurs legal obligations. As explained, we interpret section 709 of FDARA as preempting such requirements to the extent that they would require the involvement of a licensed person for consumers to access OTC hearing aids or would otherwise restrict or interfere with commercial activity involving (the servicing, marketing, sale, dispensing, use, customer support, or distribution of) OTC hearing aids.

For the reasons explained in section III.B regarding the definition of "licensed person," we are specifying certain related terms that would not on their own, as they relate to OTC hearing aids, indicate professional or specialized obligations. For example, under the proposed definition of "licensed person," identifying as a hearing aid "dispenser" would not imply licensure. Note that we would consider a person identifying as a "licensed dispenser" to be subject to State or local requirements applicable to licensed dispensers and therefore considered a "licensed person" under section 709(b)(4) of FDARA.

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The examples below focus only on the FDARA preemption provision that applies to OTC hearing aids.

a. Example 7. In contrast to identifying as a dispenser (without using the word "licensed"), as proposed, identifying as an audiologist or hearing aid fitter, for example, may imply licensure, depending on State and local requirements. Thus, a person who advertises as an audiologist or hearing aid fitter—professional

services that may be provided, but cannot be required to be provided, to sell OTC hearing aids—would be subject to State requirements that apply to audiologists or hearing aid fitters. This would be true even if such an audiologist or fitter only sold OTC hearing aids.

b. Example 8. In contrast, a person who advertises as a hearing aid dispenser or seller, and who only sells OTC hearing aids, cannot be required to obtain specialized licenses to engage in commercial activity involving OTC hearing aids.

c. Example 9. As in Example 7, a person who only sells OTC hearing aids but advertises as a licensed dispenser even though such licensing is not required to sell OTC hearing aids—the person purports to be a licensed person, not a "dispenser" more generally—would be subject to State or local requirements that apply to licensed dispensers.

We are proposing a preemption provision that speaks specifically to professional requirements in order to clarify in the regulations that the servicing, marketing, sale, dispensing, customer support, or distribution of OTC hearing aids, on its own, does not obligate a person to obtain specialized licenses, certificates, or any other State or local sanction.

H. Proposed Repeal of Conditions for Sale and Modifications for Prescription Labeling (§§ 801.420, 801.421, 801.422)

FDA is proposing to repeal the conditions for sale for hearing aids, § 801.421, because these would no longer be necessary. Currently, those conditions apply to all hearing aids, but section 520(q)(2) of the FD&C Act specifies that OTC hearing aids will be exempt from §§ 801.420 and 801.421 or any successor regulations. Instead of continuing to apply those conditions to non-OTC hearing aids, FDA is proposing to repeal them. Additionally, FDA is proposing to remove the current labeling requirements for hearing aids in § 801.420 and issue prescription labeling requirements under § 801.422, which would be in addition to the prescription labeling requirements in § 801.109.

The repeal of § 801.421 and the amendments to the labeling requirements (amending the current labeling requirements, moving them to a new section, and removing § 801.420) would have further regulatory implications. In proposing new § 801.422, FDA is not relying on its restricted device authority in section 520(e) of the FD&C Act. Therefore, if this proposed rule is finalized, class I and class II hearing aids would no longer be "restricted devices" under section 520(e) of the FD&C Act. As such, certain Federal requirements related to restricted devices would no longer apply to class I and class II hearing aids. Further, the basis for some of FDA's exemption decisions about preempted State requirements would change. The next section of this document discusses those changes along with the additional Federal preemption implications of FDARA and how we would remove, update, or clarify those regulations. Repeal of the conditions for sale would also obviate the need for the guidance entitled "Conditions for Sale for Air-Conduction Hearing Aids"; if the repeal of the conditions for sale is finalized, we would withdraw that guidance (Ref. 8).

1. REPEAL OF CONDITIONS FOR SALE § 801.421

As summarized in section I.C.2, the conditions for sale of hearing aids under § 801.421 require a statement of medical evaluation, unless waived by a user 18 years of age or older; the availability of a user instructional brochure and an opportunity to review it; and records of the statements of medical evaluation or waiver. The conditions also provide an exemption from the requirements in § 801.421 for auditory trainers.

In light of the fact that FDA is proposing to clarify that non-OTC hearing aids would be prescription devices, such hearing aids would be subject to State and local requirements for obtaining written or oral authorization of a practitioner licensed by State law to administer the use of the devices. For example, some States license audiologists to administer the use of prescription hearing aids for an adult, so adults could obtain a prescription for hearing aids from an audiologist in those States. In the case of people younger than age 18, the proposed prescription labeling statements described in the next section of this document would in manner and form emphasize the importance of medical evaluations. Because prescription hearing aids will

require a written or oral authorization from a practitioner licensed by law to administer the device, and because we are proposing certain labeling requirements in a certain manner and form, FDA is proposing to repeal the conditions for sale (including the requirement for a medical evaluation and for providing a user instructional brochure) because they would no longer be necessary to provide reasonable assurance of safety and effectiveness of prescription hearing aids. Thus, hearing aids that do not meet the definition of, or the requirements for, OTC hearing aids would all be prescription hearing aids, but they would no longer be restricted devices. We expect that the application of prescription requirements with the removal of device restrictions will not increase the burden to obtain non-OTC hearing aids, and that the change will promote consistency with other products, easing the burden on purchasers. Specifically, hearing aids will be either prescription or OTC; users and other interested people would not also need to inquire whether a device is restricted.

Additionally, repeal of the requirements discussed above would obviate the need for the exemption for group auditory trainers, which we are correspondingly proposing to repeal.

2. REVISED LABELING FOR PRESCRIPTION HEARING AIDS

We continue to believe that the labeling requirements are necessary to provide reasonable assurance of safety and effectiveness of prescription hearing aids. As such, we are proposing to retain most of the required information currently in § 801.420 in substance, except as revised below, and place the proposed revised labeling requirements that would be specific to prescription hearing aids in § 801.422, thereby removing § 801.420. These proposed revisions are to ensure that the wording is consistent with and similar to the proposed labeling statements for OTC hearing aids when appropriate. In particular, we are proposing to revise the labeling statements to be more understandable and, when addressed to users and prospective users, less technical.

In general, as summarized in section II, a device's labeling must bear adequate directions for use and certain adequate warnings in the manner and form necessary to protect the user (see section 502(f) of the FD&C Act). We 🗋 have defined "adequate directions for use," in part, as directions by which a layperson can use the device safely and for the purposes for which it is intended (see § 801.5). However, we have exempted prescription devices from the requirement for labeling to bear adequate directions for use provided they meet certain conditions (see § 801.109). For prescription devices, labeling must bear, among other statements, information for use under which practitioners licensed by law to administer the device can use it safely and for the purpose for which it is intended (see § 801.109(c)). In any case, the labeling for a device must not be false or misleading in any particular (see section 502(a)(1) of the FD&C Act). Labeling may be false or misleading because, among other reasons, it fails to reveal facts material to its use (see section 201(n) of the FD&C Act). Therefore, prescription hearing aid labeling must include certain adequate warnings as well as information for the licensed professional to use the device safely and for the purpose for which it is intended, and the labeling must not fail to reveal certain material facts.

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To determine whether those requirements are met, we consider the sale, distribution, and use of prescription hearing aids. In the case of prescription hearing aids, a prospective user would obtain one from a practitioner licensed by law in that State. However, the professional qualifications for fitters and other licensed practitioners, as well as dispensers more generally, vary widely. Therefore, we are proposing to require information for dispensers to ensure necessary warnings are conveyed in an adequate manner and form for every device. The proposal includes warnings: (1) Of possibilities for underlying pathological conditions, (2) against use in people younger than 18 without a medical evaluation, and (3) of injury potential from high output.

We are further proposing to require the disclosure of certain technical specifications, which is necessary to provide fitters and dispensers information for the safe and effective use of the device. This information is material to the use of the device, as this information would be necessary for a hearing health professional to select an appropriate device. Without this information, a hearing health professional would be unable to determine a safe and effective device for the user without unnecessarily increasing the risks to health to the

user. This provision includes a proposed requirement that measurement of the specifications conforms to ANSI/ASA S3.22-2014, "Specification of Hearing Aid Characteristics," to provide for uniformity in testing and measurement, which in turn aids hearing health professionals in selecting or fitting an appropriate prescription hearing aid.

The proposed user labeling requirements are also intended to provide adequate warnings against use in certain pathological ("red flag") conditions, and by children, where the use would be dangerous to health; as well as adequate warnings against unsafe dosage or methods or duration of administration or application. We propose that this manner and form are necessary for the protection of the users.

Once a user obtains a prescription hearing aid, use of the device occurs without direct supervision of a licensed professional, and notably, such use is generally intended to occur over long periods each day, every day. Therefore, in addition to the proposed information for hearing health professionals summarized above, we are proposing warnings and information specifically for users. We intend this information to be more understandable for laypeople while communicating warnings against use in certain pathological ("red flag") conditions, against use in children without a medical evaluation, and in a manner and form that are necessary for the protection of the users.

For the reasons explained above, we believe that the proposed labeling requirements for prescription hearing aids are necessary to provide reasonable assurance of safety and effectiveness. This proposal also maximizes consistency with OTC hearing aid labeling to reduce the burden on manufacturers that wish to offer both categories of hearing aids. Although we are proposing the foregoing warnings and information in manner and form as are necessary for the protection of users, the specificity of this proposal would also encourage uniformity while conveying essential information appropriate for the type of hearing healthcare delivery. By minimizing burdens and fostering familiarity, the specificity and consistency would also help promote availability and use of prescription devices.

To provide for clarity and efficient enforcement of the FD&C Act, FDA is proposing to provide explicitly that a prescription hearing aid that does not satisfy the labeling requirements of proposed § 801.422, if finalized, would be misbranded under sections 201(n), 502(a), and 502(f) of the FD&C Act. Moreover, as explained, we believe that the labeling statements as we propose to revise them are material to and necessary for the safe and effective use of prescription hearing aids. Thus, we believe that an explicit misbranding provision in the prescription labeling requirements will provide for clarity as well as the efficient enforcement of the FD&C Act.

If we finalize the repeal of the conditions for sale under § 801.421, we would correspondingly withdraw the guidance document entitled "Conditions for Sale for Air-Conduction Hearing Aids" because that guidance announces our policy regarding certain provisions of § 801.421 and would cease to be relevant (Ref. 8).

I. Proposed Amendments to Previous Exemption Decisions (Part 808)

A State or a political subdivision (*e.g.,* a city) may not establish or continue in effect its own requirement with respect to a device for human use if that requirement is different from, or in addition to, a requirement applicable under the FD&C Act to the device (see section 521(a) of the FD&C Act). Under section 521(b) of the FD&C Act, upon application of a State or political subdivision of a State, FDA may, by regulation, exempt from preemption a State or political subdivision requirement applicable to a device if: (1) The requirement is more stringent than a requirement under the FD&C Act that would be applicable to the device if an exemption were not in effect or (2) the requirement is required by compelling local conditions and compliance with the requirement would not cause the device to be in violation of the FD&C Act. FDA has granted some exemption requests and most, if not all, of FDA's decisions to grant exemption from preemption were based on the State or local requirement being more stringent.

FDA's decisions on States' applications for exemption from Federal preemption under section 521 of the FD&C Act are codified in regulations under part 808, subpart C. The regulations codifying these decisions include both granting and denial of exemption from preemption. Therefore, “exemption decisions” as used in this document include both types of decisions. Most of the applications for exemption from Federal preemption related to State medical device requirements that apply to hearing aids, as they existed at the time of the exemption decisions, and that were different from or in addition to the requirements in §§ 801.420 and/or 801.421. Because FDARA directs FDA to establish different requirements for some hearing aids that are not subject to section 521(b) of the FD&C Act, many of the current exemption decisions would not accurately reflect the regulatory framework for hearing aids under FDARA and the FD&C Act as amended. Moreover, if we finalize the changes we are proposing to the existing requirements for hearing aids in §§ 801.420 and 801.421, the previous exemption decisions based on those requirements may no longer apply.

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1. EXEMPTION DECISIONS UNDER SECTION 521(B) ARE AFFECTED BY FDARA (PROPOSED § 808.1(G))

As explained in section III.G of this document, and as indicated above, some decisions on exemption from Federal preemption under section 521(b) of the FD&C Act would no longer accurately reflect the applicability of State requirements after the enactment of FDARA and upon establishing the OTC category of hearing aids. To assist stakeholders to understand the changes effected by FDARA, we are proposing to codify how FDARA limits the scope of exemption decisions under section 521(b) of the FD&C Act. We believe this proposal will provide a concise reference for stakeholders to ascertain the changes effected by FDARA.

Note that we are not considering exemptions from section 709(b)(4) of FDARA for State or local requirements. This is because FDARA does not provide a parallel mechanism to exempt State or local requirements regarding hearing products that would restrict or interfere with commercial activity involving OTC hearing aids. We refer to preemption under section 709(b)(4) simply to clarify how FDARA affects State and local requirements.

2. REMOVAL OF REGULATIONS CODIFYING EXEMPTION DECISIONS AFFECTED BY AMENDMENTS TO § 801.420 AND REPEAL OF § 801.421 IF FINALIZED

As explained above, FDA's exemption decisions are codified in regulations under part 808, subpart C. These decisions were issued in the 1980s and apply to the specific State provisions identified in the regulations and the specific Federal requirements in effect at the time. As mentioned above, most of the exemption decisions related to State medical device requirements that apply to hearing aids and that were different from or in addition to the requirements in §§ 801.420 and/or 801.421. We are proposing to remove all of the regulations in part 808 related to hearing aids; that is, almost all regulations codifying the previous decisions in §§ 808.53 through 808.101, except for the portions of § 808.55 (California) that do not relate solely to hearing aids. We are proposing this because the exemption decisions codified in those regulations may no longer apply due to changes to the Federal hearing aid requirements as proposed in this rulemaking and changes to the specific State provisions we have identified in those regulations since the decisions were made over 30 years ago.

In particular, the repeal of the conditions for sale would eliminate specific Federal requirements that preempt certain State or local requirements. As such, whether we previously granted or denied exemptions, the exemption decisions would no longer apply because the State or local requirements that differed from, or were in addition to, § 801.421 would no longer be preempted. Therefore, we are proposing to remove the State-specific regulations in part 808 codifying exemption decisions pertaining to the conditions for sale for hearing aids because those decisions would no longer be applicable if the conditions for sale are repealed.

Also, the proposed amendments to the hearing aid labeling requirements may affect the exemption decisions relating to § 801.420. Although the proposed § 801.422 is similar to § 801.420 in that it too would address labeling for hearing aids, the labeling requirements are not identical to those in § 801.420 and include substantive changes. Moreover, FDA is aware that several States have modified their requirements that were

the subject of the exemption decisions since they applied for exemptions, in which case the exemption decision may no longer be applicable. Thus, not only will the Federal requirements change, but the State requirements that were the subject of the exemption decisions may have changed too since the decisions were made.

Given that the exemption decisions were based on specific Federal requirements and specific State requirements that existed at the time of the decision, changes in either may affect those decisions such that they are no longer applicable. Because the exemption decisions relating to hearing aid labeling requirements may no longer be applicable, we are proposing to remove the regulations codifying these decisions. We specifically seek comments from the States regarding the proposed removal of the regulations in part 808, subpart C, codifying these exemption decisions. For example, if a State disagrees with the proposed removal of the regulation(s) in part 808, subpart C, because the State believes the exemption decision still applies, a statement and explanation why in the comments may be helpful.

We note that when § 801.422 is finalized and in effect, no State or political subdivision of a State may establish or continue in effect with respect to prescription hearing aids, any requirement which is different from, or in addition to, any requirement in § 801.422 (see section 521(a) of the FD&C Act). However, a State or political subdivision thereof may apply for an exemption from preemption by following the process in part 808 for any requirement that is preempted by § 801.422 (see also section 521(b) of the FD&C Act).

J. Other Proposed Amendments

FDA is proposing several amendments to provide for consistency, including with the proposals in this rulemaking, if finalized, and to improve clarity. We are proposing the following:

- To realign the hearing aid classification regulations by sound conduction mode so that legacy air-conduction hearing aids, wireless air-conduction hearing aids, and self-fitting air-conduction hearing aids would be under one classification regulation; bone-conduction hearing aids would be under a separate classification regulation.
- To clarify that air-conduction hearing aids are subject to § 800.30 or § 801.422, as applicable, and bone-conduction hearing aids are subject to § 801.422.
- To revise the special control currently in § 874.3305(b)(1) for consistency with the special control currently in § 874.3325(b)(3). Although the proposed revision to § 874.3305(b)(1) would require demonstration of electrical safety and thermal safety, we believe that generally manufacturers of wireless air-conduction hearing aids regulated under § 874.3305 have been evaluating these safety aspects for their devices and therefore, this proposed revision would have little to no impact on these manufacturers.
- To revise the special controls for wireless hearing aids currently in § 874.3305(b) and for self-fitting hearing aids currently in § 874.3325(b) to eliminate redundancy, for example, removing special controls that would be addressed by the proposed labeling requirements for both OTC and prescription hearing aids.
- To revise §§ 874.3315 and 874.3950 to clarify that these devices are subject to the prescription hearing aid labeling requirements, including in proposed § 801.422.

• To clarify that a tympanic membrane contact hearing aid under § 874.3315 is a wearable device for purposes of prescription hearing aid labeling.

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We are also proposing non-substantive modifications to the decisions regarding exemption from Federal preemption in part 808 to assist stakeholders to understand the subject matter of the individual exemption decisions.

1. REALIGNMENT OF HEARING AID CLASSIFICATION REGULATIONS BY SOUND CONDUCTION MODE

To increase clarity and to reduce administrative burdens associated with interpreting regulations, we are proposing to separate the classification regulations for bone-conduction and air-conduction hearing aids. We believe this will increase clarity because air-conduction devices are technologically more similar to each other than they are to bone-conduction devices. In addition, section 520(q)(1)(A)(i) defines an OTC hearing aid as

a device that, among other criteria, uses the same fundamental scientific technology as air-conduction hearing aids that are wearable devices. Therefore, bone-conduction hearing aids do not fall within the scope of the OTC hearing aid definition and moving them to a separate classification regulation (proposed § 874.3301) will help make that clear. Tympanic membrane contact hearing aids also do not fall within the scope of the OTC hearing aid definition because, among other reasons, they do not use the same fundamental scientific technology as air-conduction hearing aids, and as specified in § 874.3315, they will continue to be regulated as prescription devices.

The proposed realignment of the air-conduction hearing aid types would also locate all OTC hearing aids within the same classification regulation; however, not all air-conduction hearing aids would be OTC hearing aids. For example, high-output air-conduction devices would be prescription. Further, transcutaneous air conduction hearing aid systems entail surgical implantation of a tube to conduct sound, so we do not consider them suitable for OTC availability; the devices will continue to be regulated under § 874.3950. The realignment will not affect any device that does not use the same fundamental scientific technology, such as cochlear implants (product code MCM) or implantable middle ear hearing devices (product code MPV).

In realigning the regulations by sound conduction mode, we are not proposing to reclassify any device or change the exemption status under section 510(m)(2) of the FD&C Act for premarket notification for any device type (see 21 U.S.C. 360 (https://www.govinfo.gov/link/uscode/21/360?type=usc&year=mostrecent&link-type=html)(m)(2)). For example, wireless air-conduction hearing aids regulated under § 874.3305 would continue to be class II exempt, subject to the limitations of exemption in § 874.9, and special controls would continue to apply to these devices in addition to the general controls. (The proposed general controls under § 800.30 or § 801.422, if finalized, would also apply.) As of the effective date of the final rule, we would realign current product codes to correspond with the revised regulation numbers for consistency but would not otherwise change the codes. Also, we would change the name of each classification regulation to reflect the sound conduction mode.

Note that the regulation for air-conduction hearing aids would embody a split classification, where different devices under the regulation would have different classifications and special controls depending on the technology and design. As discussed above, we would also amend the wireless hearing aid special controls to provide for consistency with the special controls for self-fitting hearing aids, and we would amend the special controls for wireless hearing aids and self-fitting hearing aids to eliminate redundancy.

2. NON-SUBSTANTIVE REVISIONS TO EXEMPTION DECISIONS FOR CLARITY AND EASE OF USE

In addition to the amendments in part 808 explained in section III.I., we are proposing to amend the remaining State-specific regulation in part 808 to include paragraph headings that would appear in italics. Currently, the regulations do not include paragraph headings and, as such, require stakeholders to look elsewhere to understand the content of the State or local requirements as they were at the time FDA made an exemption decision. The paragraph headings will assist stakeholders by briefly describing the subject of the individual exemption decisions, thereby providing additional information and context for stakeholders.

IV. Findings Regarding Premarket Notification

FDA may, in appropriate circumstances, exempt a class II device from premarket notification requirements under section 510(m)(2) of the FD&C Act. Section 709(b)(3) of FDARA directs FDA to make such findings, that is, to determine whether OTC hearing aids require a report under section 510(k) to provide reasonable assurance of safety and effectiveness. As described in section I.B, legacy and wireless air-conduction hearing aids are exempt from section 510(k) subject to the limitations of exemption, and we are not proposing to alter the exemption status of such devices.

Self-fitting air-conduction hearing aids are not currently exempt. FDA classified this device type in October 2019 (see 84 FR 57610 (/citation/84-FR-57610)), and the Agency does not have sufficient information or experience with this device type to exempt these devices from premarket notification. Accordingly, FDA has

determined that, at this time, reports under section 510(k) continue to be necessary to provide reasonable assurance of safety and effectiveness. We therefore do not propose to exempt them at this time.

V. Proposed Effective and Compliance Dates

A. Effective Date

FDA proposes that this rule, if finalized, be effective 60 days after the publication of the final rule in the **Federal Register** . We propose the following compliance dates:

B. Compliance Date for Hearing Aids Not Legally Offered for Sale Prior to the Effective Date

For hearing aids that have not been offered for sale prior to the effective date of the final rule, or have been offered for sale but are required to submit a new 510(k) under 21 CFR 807.81 (/select-citation/2021/10/20/21-CFR-807.81)(a)(3), compliance with the new or revised requirements applicable to the hearing aid, and obtaining 510(k) clearance if applicable, must be achieved before marketing the device on or after the effective date of the final rule. If a person (*e.g.,* manufacturer) markets such a device without complying with the new or revised requirements or if applicable, receiving 510(k) clearance, then FDA would consider taking action against such person under our usual enforcement policies.

C. Compliance Date for Hearing Aids Legally Offered for Sale Prior to the Effective Date

For hearing aids that have been legally offered for sale prior to the effective date of the final rule, including those that already have a 510(k) clearance, compliance with the new or revised requirements that apply to the hearing aid must be achieved 180 days after the effective date of the final rule (*i.e.,* 240 days after the publication of the final rule). After that date, if a person (*e.g.,* manufacturer) continues to market such a device but does not comply with the new or revised requirements that apply to the device, then FDA would consider taking action 🗋 against such person under our usual enforcement policies.

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At present, legacy and wireless air-conduction hearing aids are exempt from section 510(k) of the FD&C Act, subject to the limitations of exemption described in § 874.9. (Legacy hearing aids are class I devices and are 510(k) exempt under section 510(*l*)(1) of the FD&C Act.) However, self-fitting air-conduction hearing aids are not exempt and, therefore, are subject to premarket notification requirements. We believe that modifications to hearing aids, including labeling changes, to comply with the proposed OTC Hearing Aid Controls may exceed the limitations of exemption, for example because the device was formerly intended for use by healthcare professionals only. We believe that labeling changes for such hearing aids to comply with the proposed prescription hearing aid labeling requirements are less likely to exceed the limitations of exemption.

VI. Preliminary Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, (/executive-order/13563) the Regulatory Flexibility Act (5 U.S.C. 601 (https://www.govinfo.gov/link/uscode/5/601?type=usc&year=mostrecent&link-type=html)-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4 (https://www.govinfo.gov/link/plaw/104/public/4?link-type=html)). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Based on our preliminary analysis, OMB's Office of Information and Regulatory Affairs has determined that this proposed rule is an economically significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. We believe we can certify that the proposed rule will not have a significant economic impact on a substantial number of small entities. The estimated annualized cost over 10 years is $0.009 million per firm, which is unlikely to represent more than 3 percent to 5 percent of the revenue of an

affected manufacturer. However, we note that some uncertainty exists as to these impacts, so we have chosen to draft an initial regulatory flexibility analysis. We request comments relating to the effect of this proposed rule on small manufacturers.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

The proposed rule, if finalized, would define a new regulatory category for OTC hearing aids and make corresponding changes to the existing regulatory framework, including defining hearing aids not meeting the proposed OTC requirements as prescription medical devices, as well as providing new labeling requirements for both OTC and prescription hearing aids. This proposed rule, if finalized, would generate potential cost savings for consumers with perceived mild to moderate hearing loss who wish to buy lower cost hearing aids not bundled with professional services and not requiring professional advice, fitting, adjustment, or maintenance but who are currently unable to buy such products online because of State regulations or because they do not shop online. The proposed rule, if finalized, would also generate costs for hearing aid manufacturers for changing labeling of existing hearing aids as well as for reading the rule and revising internal standard operating procedures in response to the rule. Table 3 summarizes our estimate of the annualized costs and the annualized benefits of the proposed rule, if finalized.

Table 3—Summary of Benefits, Costs and Distributional Effects of Proposed Rule

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits:							
Annualized Monetized $millions/year	$63 63	$6 6	$147 147	2020 2020	7 3	10 10	
Annualized Quantified					7 3		
Qualitative	Potential increase in hearing aid and hearing technology use, leading to associated health benefits, potential fostering of innovation in hearing aid technology.						
Costs:							
Annualized Monetized $millions/year	1 1	1 1	2 2	2020 2020	7 3	10 10	
Annualized Quantified					7 3		
Qualitative	Potential loss of consumer utility from inability to buy existing hearing aids under existing conditions						
Transfers:							
Federal Annualized Monetized $millions/year					7 3		
From/To	From:			To:			
Other Annualized Monetized $millions/year					7 3		
From/To	From:			To:			

Effects:

State, Local or Tribal Government:

Small Business:

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full analysis of economic impacts is available in the docket for this proposed rule (Ref. 23) and at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations (https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations)*.

VII. Analysis of Environmental Impact

FDA has carefully considered the potential environmental impact of this proposed rule and of possible alternative actions. In doing so, the Agency focused on the environmental impacts of its action as a result of increased use and eventual disposal of OTC hearing aids that will need to be handled if the proposed rule is finalized.

The environmental assessment (EA) considers environmental impacts related to additional waste to landfills at municipal solid waste (MSW) facilities. The proposed action would increase the availability and use of hearing aid devices, which would result in additional waste from increased disposal of these devices and their associated batteries and an increase in industrial waste associated with any domestic production to meet market demand for the new devices. Overall, given the current limited use of these devices, projected slow growth with increase in availability, and the small mass of waste material to be disposed or recycled, the proposed action is not expected to have a significant impact on MSW, landfill facilities, and the environment.

The Agency has concluded that the proposed rule will not have a significant impact on the human environment, and that an environmental impact statement is not required. FDA's finding of no significant impact (FONSI) and the evidence supporting that finding, contained in an EA prepared under 21 CFR 25.40 (/select-citation/2021/10/20/21-CFR-25.40), are on display with the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov (https://www.regulations.gov)*. FDA invites comments and submission of data concerning the EA and FONSI.

VIII. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the PRA (44 U.S.C. 3501 (https://www.govinfo.gov/link/uscode/44/3501?type=usc&year=mostrecent&link-type=html)-3521). A description of these provisions is given in the *Description* section of this document with an estimate of the annual recordkeeping and third-party disclosure burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering, and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Medical Device Labeling Regulations; OMB Control Number 0910-0485—Revision.

Description: FDA is proposing to establish a regulatory category and related rules for OTC hearing aids to improve access to hearing aid technology for Americans. FDARA amended the FD&C Act by placing the authorities to establish the OTC category of hearing aids among provisions that are, by definition, general controls, which is what these rules would be. Alongside the OTC category, we are proposing multiple related changes to the overall regulatory framework for hearing aids to harmonize existing rules with the eventual OTC category while continuing to provide a reasonable assurance of safety and effectiveness. We believe the proposals set forth in this rulemaking will promote the hearing health of Americans by lowering barriers to

access and fostering innovation in hearing aid technology. The set of general controls we are proposing, Over-the-Counter Hearing Aid Controls, would apply to all hearing aids that meet the definition of an OTC hearing aid under the FD&C Act, regardless of the device's class. Among other provisions, the controls would include requirements for labeling and device design, as well as a condition for sale to prevent the sale and use of the devices by people younger than age 18. We are also proposing to remove the labeling requirements in the existing restrictions but establish a new regulation for labeling specific to prescription hearing aids. The new prescription labeling requirements would be similar to the current labeling requirements but maintain consistency with the new labeling requirements for OTC hearing aids (for example, so that "red flag" conditions, as revised, will be the same). We are proposing to repeal the other existing restrictions, *i.e.,* the conditions of sale, because, if this rule is finalized as proposed, the new labeling requirements for prescription hearing aids, the requirement for a prescription, and other existing requirements would provide reasonable assurance of safety and effectiveness.

Description of Respondents: Respondents to the information collection are manufacturers of hearing aids. 🗋 🗋 Start Printed Page 58174

We estimate the burden of the collection of information as follows:

Table 4—Estimated One-Time Burden [1] [2]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours	Total capital costs
Understanding and implementing new regulatory requirements from hearing aids rule	105	1	105	284	29,820	$4,100,000
Hearing aids relabeling; one-time burden	105	8	840	68	57,120	6,000,000

[1] *There are no operating and maintenance costs associated with this collection of information.*

[2] *Numbers have been rounded to the nearest whole number.*

Table 5—Estimated Annual Recordkeeping Burden [1] [2]

Activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Proposed labeling disclosures under 800.30(c)(2) and 801.422(c)(2); Hearing aids; electronic version of user instructional brochure	105	8	840	1	840

[1] *There are no capital costs or operating and maintenance costs associated with this collection of information.*

[2] *Numbers have been rounded to the nearest whole number.*

Table 6—Estimated Annual Third-Party Disclosure Burden [1] [2]

Activity; 21 CFR Section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
OTC Hearing Aid Controls—800.30	105	7	735	19	13,965
Prescription Hearing Aid Labeling—801.422	105	1	105	19	1,995
Total					15,960

[1] *There are no capital costs or operating and maintenance costs associated with this collection of information.*

[2] *Numbers have been rounded to the nearest whole number.*

Our burden estimate is based on FDA Uniform Registration and Listing System data; FDA's Operational and Administrative System for Import Support data; informal communications with industry; and our knowledge of and experience with information collection pertaining to medical device labeling. We intend the burden estimates to be consistent with our Preliminary Regulatory Impact Analysis (PRIA) for this rulemaking (Ref. 23).

Estimated One-Time Burden: OTC Hearing Aids proposed rule—one-time burden (Recordkeeping): As noted in the PRIA for this proposed rule, we estimate it will take 3 hours each for an executive, a lawyer, and a marketing manager to read and understand the rule. Also included in our estimate is time for revising guidelines or standard operating procedures. We assume this may take up to 25 hours for one executive, up to 100 hours for one marketing manager, and up to 150 hours for one technical writer. Therefore, we estimate a one-time recordkeeping burden of 284 hours for each manufacturer.

OTC Hearing Aids proposed rule — one-time relabeling burden (Third-Party Disclosure):

The proposed rule would necessitate the relabeling of all current hearing aids (approximately 840). The labeling cost model used in the PRIA suggests, based on a compliance period of 6 months, a one-time estimated third-party disclosure burden for relabeling of about 68 hours per product.

We request comments on these estimates.

Estimated Annual Burden: Over-the-Counter Hearing Aid Controls—§ 800.30 (Recordkeeping and Third-Party Disclosure): Proposed § 800.30 sets forth labeling requirements for OTC hearing aids. Proposed § 800.30(c)(1) describes the warnings and other important information that the outside package must bear. Additionally, manufacturers must include on the outside package label a weblink to all labeling and any additional resources, their return policy or lack thereof, and, if the OTC hearing aid is used or rebuilt, they must declare that fact.

Proposed § 800.30(c)(2) describes device-specific requirements for labeling, inside the package. Among the labeling requirements listed are a user instructional brochure, an electronic version of which is to be made available for download; additional warnings; caution and notices for users; other specified information; and any other information necessary for adequate directions for use as defined in § 801.5. Also required under proposed § 800.30(c)(2) is the identification of any known physiological side effects associated with the use of the OTC hearing aid that may warrant consultation with a physician; the technical specifications required by § 800.30(c)(4); a description of commonly occurring, avoidable events that could adversely affect or damage the OTC hearing aid; if applicable, information regarding repair service; and, if applicable, a summary of all clinical or non-clinical studies 🗋 conducted to support the performance of the OTC hearing aid.

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Proposed § 800.30(c)(3) provides requirements for the labeling on an OTC hearing aid itself, specifically, name of the manufacturer, model name or number, serial number, and year of manufacture and if applicable, information regarding the battery. Also, if the OTC hearing aid is used or rebuilt, the manufacturer must physically attach a removable tag to the hearing aid declaring that fact.

We include no estimate for provisions under proposed § 800.30(c)(1)(i)(A) through (D), (c)(2)(i)(A) and (B), and (c)(2)(iii)(A) through (D) because we consider the labeling to be "public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public," consistent with 5 CFR 1320.3 (/select-citation/2021/10/20/5-CFR-1320.3)(c)(2). Thus, those labeling provisions are not within the definition of collection of information.

The PRIA for this proposed rule estimates that 105 firms manufacture air-conduction hearing aids sold in the United States, based on FDA Medical Device Registration data. We estimate that each manufacturer has an average of eight products that would need relabeling.

For each hearing aid product, we assume a 1-hour annual recordkeeping burden for maintaining the electronic version of the user instructional brochure (under proposed §§ 800.30(c)(2) and 801.422(c)(2)).

The proposed rule would necessitate the relabeling of all current hearing aids (approximately 840) according to either the proposed OTC or prescription hearing aid labeling requirements. While we lack specific data regarding what portion of hearing aids will be relabeled as prescription devices and what portion will be relabeled as OTC hearing aids, for this analysis, we assume that 10 percent will be relabeled as prescription medical devices (about 1 product per manufacturer) and 90 percent as OTC hearing aids (about 7 products per manufacturer). The labeling cost model used in the PRIA suggests an annual estimated third-party disclosure burden of about 19 hours per product.

We request comments on these estimates and assumptions.

Prescription Hearing Aid Labeling—§ 801.422 (Third-Party Disclosure):

Proposed § 801.422(c) sets forth labeling requirements for prescription hearing aids. However, as with some of the provisions under proposed § 800.30(c), we include no estimate for provisions under proposed § 801.422(c)(1)(i)(A) and (B), (c)(2)(i)(A) through (C), and (c)(2)(ii)(A) through (E) because we consider the labeling to be "public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public," consistent with 5 CFR 1320.3 (/select-citation/2021/10/20/5-CFR-1320.3)(c)(2).

Proposed § 801.422(c)(1) provides the warnings that must be on the outside package labeling and, if applicable, that the prescription hearing aid is used or rebuilt.

Proposed § 801.422(c)(2) describes requirements for prescription hearing aid labeling, inside the package. Among the labeling requirements listed are a user instructional brochure, an electronic version of which is to be made available for download; additional warnings; caution and notices for users; and additional information that must be included in the user instructional brochure.

Proposed § 801.422(c)(3) provides the requirements for the labeling on a prescription hearing aid itself, specifically, name of the manufacturer, model name or number, serial number, and year of manufacture; as well as information regarding the battery if applicable; and if the prescription hearing aid is used or rebuilt, the manufacturer must physically attach a removable tag to the hearing aid declaring that fact.

Proposed § 800.422(c)(4) provides the technical specification elements that must appear in the user instructional brochure or in separate labeling that accompanies the device.

The PRIA estimates that 105 firms manufacture air conduction hearing aids sold in the United States, based on FDA Medical Device Registration data. We estimate that each manufacturer has an average of eight products that would need relabeling.

For each hearing aid product, we assume a 1-hour annual recordkeeping burden for maintaining the electronic version of the user instructional brochure (under proposed §§ 800.30(c)(2) and 801.422(c)(2)).

The proposed rule would necessitate the relabeling of all current hearing aids (approximately 840) according to either the proposed OTC or prescription hearing aid labeling requirements. While we lack specific data regarding what portion of hearing aids will be relabeled as prescription devices and what portion will be relabeled as OTC hearing aids, for this analysis, we assume that 10 percent will be relabeled as prescription medical devices (about 1 product per manufacturer) and 90 percent as OTC hearing aids (about 7 products per manufacturer). The labeling cost model used in the PRIA suggests an annual estimated third-party disclosure burden of about 19 hours per product.

We request comments on these estimates and assumptions.

To ensure that comments on information collection are received, OMB recommends that written comments be submitted through *https://www.reginfo.gov/public/do/PRAMain (https://www.reginfo.gov/public/do/PRAMain)* (see **ADDRESSES**). All comments should be identified with the title of the information collection.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407 (https://www.govinfo.gov/link/uscode/44/3407?type=usc&year=mostrecent&link-type=html)(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These information collection requirements will not be effective until FDA publishes a final rule, OMB approves the information collection requirements, and the rule goes into effect. FDA will announce OMB approval of these requirements in the **Federal Register** .

IX. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132 (/executive-order/13132). Section 4(a) of the Executive Order requires Agencies to "construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or where there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute." Federal law includes an express preemption provision that preempts certain state requirements "different from, or in addition to, any requirement applicable under" chapter V of the FD&C Act that is applicable to devices. (See section 521 of the FD&C Act; *Medtronic* v. *Lohr,* 518 U.S. 470 (1996); and *Riegel* v. *Medtronic,* 552 U.S. 312 (2008)). Federal law also preempts State or local laws "specifically related to hearing products that would restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of [OTC hearing aids] through in-person transactions, by mail, or online, that [are] different from, in addition to, or otherwise not identical to, the regulations promulgated under" section 709(b) of FDARA (see section 709(b)(4) of FDARA).

Section 521(b) of the FD&C Act provides that the Commissioner of Food and Drugs may, upon application of a State or local government, exempt a requirement from preemption, if the State or local requirement for the device is more stringent than the requirement 🗋 under the FD&C Act, or if the requirement is necessitated by compelling local conditions and compliance with it would not cause the device to be in violation of a requirement under the FD&C Act." Following this process, and if this rule becomes final, a State or local government may request an exemption from preemption for those State or local requirements pertaining to hearing aid products that are preempted by the Agency's final rule under section 521 of the FD&C Act. However, because FDARA does not provide a parallel mechanism to exempt State or local requirements from its express preemption provision, FDA is not considering exemptions under section 709(b)(4) of FDARA for OTC hearing aids.

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Thus, if this proposed rule is made final, the final rule would create requirements that fall within the scope of section 521 of the FD&C Act and/or section 709(b)(4) of FDARA. If made final, it would also amend § 801.420 and repeal § 801.421, and such changes would affect many of the decisions on applications for exemption from preemption that were issued in relation to these two regulations under section 521(b) of the FD&C Act, resulting in the removal of the regulations codifying such decisions, as discussed further in section III.I. above. The scope of preemption of this proposed rule, if finalized, is discussed in more detail in sections III.G through I, above.

X. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175 (/executive-order/13175). We have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal

Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XI. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov (https://www.regulations.gov)*. References without asterisks are not on public display at *https://www.regulations.gov (https://www.regulations.gov)* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only with the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register** , but websites are subject to change over time.

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List of Subjects

21 CFR Part 800 (/select-citation/2021/10/20/21-CFR-800)

- Administrative practice and procedure
- Incorporation by reference
- Medical devices
- Ophthalmic goods and services
- Packaging and containers
- Reporting and recordkeeping requirements

21 CFR Part 801 (/select-citation/2021/10/20/21-CFR-801)

- Incorporation by reference
- Labeling
- Medical devices
- Reporting and recordkeeping requirements

21 CFR Part 808 (/select-citation/2021/10/20/21-CFR-808)

- Intergovernmental relations
- Medical devices

21 CFR Part 874 (/select-citation/2021/10/20/21-CFR-874)

- Medical devices

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR parts 800 (/select-citation/2021/10/20/21-CFR-800), 801, 808, and 874 be amended as follows:

PART 800—GENERAL

1. The authority citation for part 800 is revised to read as follows:

Authority: 21 U.S.C. 321 (https://www.govinfo.gov/link/uscode/21/321?type=usc&year=mostrecent&link-type=html), 334, 351, 352, 355, 360e, 360i, 360j, 360k, 361, 362, 371.

Section 800.30 also issued under Sec. 709, Pub. L. 115-52 (https://www.govinfo.gov/link/plaw/115/public/52?link-type=html), 131 Stat. 1065-67.

2. Add § 800.30 to subpart B to read as follows:

§ 800.30 Over-the-Counter Hearing Aid Controls.

(a) *Scope.* This section specifies the requirements for over-the-counter (OTC) air-conduction hearing aids. Air-conduction hearing aids that satisfy the requirements in paragraphs (c) through (f) of this section are considered "available" over the counter as section 520(q)(1)(A)(v) of the Federal Food, Drug, and Cosmetic Act uses the term. Air-conduction hearing aids that do not meet the definition in section 520(q) of the Federal Food, Drug, and Cosmetic Act and do not satisfy the following requirements are prescription hearing aids. Unless otherwise specified, the requirements in this section are in addition to other applicable requirements, including but not limited to special controls found in the applicable classification regulation.

(b) *Definitions for the purposes of this section.* This section uses the following definitions:

Air-conduction hearing aid. An air-conduction hearing aid is a hearing aid that conducts sound to the ear through the air.

Hearing aid. A hearing aid is any wearable device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing.

Licensed person. A licensed person is a person as defined in section 201(e) of the Federal Food, Drug, and Cosmetic Act that holds a license or degree for the diagnosis, assessment, or treatment of hearing loss; or that holds a license to sell or distribute hearing aids. A person that must meet generally applicable licensing or operating requirements such as annual health and safety inspections, provided the generally applicable licensing or operating requirement is consistent with this section and other applicable requirements under the Federal Food, Drug, and Cosmetic Act, is not a "licensed person" solely for that reason. A person that represents as a marketer, seller, dispenser, distributor, or customer support representative (or an equivalent description) is not a "licensed person" solely by making such representations.

Over-the-counter hearing aid. An over-the-counter (OTC) hearing aid is an air-conduction hearing aid that does not require implantation or other surgical intervention, and is intended for use by a person age 18 or older to compensate for perceived mild to moderate hearing impairment. The device, through tools, tests, or software, allows the user to control the hearing aid and customize it to the user's hearing needs. The device may use wireless technology or may include tests for self-assessment of hearing loss. The device is available over-the-counter, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online, provided that the device satisfies the requirements in this section.

Prescription hearing aid. A prescription hearing aid is a hearing aid that is not an OTC hearing aid as defined in this section or a hearing aid that does not satisfy the requirements in this section.

Sale. Sale includes a lease, rental, or any other purchase or exchange for value.

Tools, tests, or software. Tools, tests, or software are components of the device that, individually or in combination, allow a lay user to control the device and customize it sufficiently, such as the device's output, to meet the user's hearing needs.

Used hearing aid. A hearing aid is "used" if a user has worn it for any period of time. However, a hearing aid shall not be "used" merely because a prospective user wore it as part of a bona fide hearing aid evaluation to determine whether to select that particular hearing aid for that prospective user. A hearing aid evaluation is "bona fide" if it was conducted in the presence of the dispenser or a hearing health professional selected by the dispenser to assist the prospective user in making a determination.

(c) *Labeling*. An OTC hearing aid shall bear all of the following in the labeling.

(1) *Outside package labeling*. The outside package of an OTC hearing aid shall bear all of the following:

(i) *Warnings and other important information*. All of the following shall appear on the outside package:

(A) *Warning against use in people younger than 18.*--

WARNING: If you are younger than 18, do not use this.

You should go to a doctor because your condition needs specialized evaluation and management. Over-the-counter hearing aids are only for users who are age 18 or older.

(B) *Symptoms suggesting perceived mild to moderate hearing loss.*--

This hearing aid is designed and intended for perceived mild to moderate hearing loss in adults. If you experience any of the following, you may have this kind of hearing loss:

- Difficulty hearing or understanding conversations, especially in groups or noisy places, or when you can't see who is talking
- Difficulty hearing while using a telephone
- Fatigue due to greater listening effort
- Needing to turn up the volume of television, radio, or music louder than normal or loud enough for others to complain

(C) *Advice of availability of professional services.*--

Important Information: You can seek assistance from a hearing healthcare professional.

This device may not be useful for more significant hearing loss or complicated hearing needs. If you cannot hear conversations in a quiet environment, or you have trouble hearing loud sounds—for example, loud music, motor vehicles, power tools, noisy appliances—this device may not help you hear better. If you try this device and continue to struggle with or remain concerned about your hearing, you should seek a consultation with a hearing healthcare professional.

(D) *"Red flag" conditions.*--

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WARNING: Conditions that Require Medical Care

Prior to purchasing this device, you should promptly consult with a licensed physician, preferably an ear specialist, if you have any of the following:

- Visible deformity of the ear, either present since birth or from trauma
- Fluid, pus, or blood coming out of the ear in the past 6 months
- Pain or discomfort in the ear
- History of excessive ear wax or suspicion that something is in the ear canal
- Episodes of vertigo (a sensation of spinning or swaying) or severe dizziness
- Sudden, quickly worsening, or fluctuating hearing loss in the past 6 months
- Hearing loss or ringing (tinnitus) only in one ear or a noticeable difference in hearing between ears

(E) *Notice of weblink and telephone number for information.*--

This information and other labeling, including the user instructional brochure, are available on the internet at: [weblink to all labeling and any additional resources]

You may also call [telephone number] to request a paper copy of this information and other labeling.

(F) *Notice of manufacturer's return policy.*--

Manufacturer's return policy: [succinct, accurate statement of return policy or absence of return policy]

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(ii) *Statement of build condition.* If the OTC hearing aid is used or rebuilt, the outside package shall declare that fact. A sticker under and visible through the outer wrapper will suffice to declare such fact.

(2) *Labeling, inside the package.* The manufacturer or distributor of an OTC hearing aid shall include a user instructional brochure inside the package and shall make an electronic version available for download without site or customer registration and without requiring purchase of any product or service. The user instructional brochure shall include all of the following:

(i) The following warnings, which shall appear in the following order and prior to any content except the cover page:

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(A) *Warning against use in people younger than 18.*--

WARNING: If you are younger than 18, do not use this. You should go to a doctor because your condition needs specialized evaluation and management. Over-the-counter hearing aids are only for users who are age 18 and older.

This over-the-counter hearing aid is for users age 18 and older to compensate for perceived mild-to-moderate hearing impairment. A younger person with hearing loss should see a licensed physician, preferably an ear specialist, for diagnosis of potential associated medical conditions. Furthermore, children should receive a formal hearing evaluation and rehabilitation since hearing loss may cause problems in language development and educational and social growth of a child.

(B) *"Red flag" conditions.*--

WARNING: Conditions that Require Medical Care

Prior to purchasing this device, you should promptly consult with a licensed physician, preferably an ear specialist, if you have any of the following:

- Visible deformity of the ear, either present since birth or from trauma
- Fluid, pus, or blood coming out of the ear in the past 6 months
- Pain or discomfort in the ear
- History of excessive ear wax or suspicion that something is in the ear canal
- Episodes of vertigo (a sensation of spinning or swaying) or severe dizziness
- Sudden, quickly worsening, or fluctuating hearing loss in the past 6 months
- Hearing loss or ringing (tinnitus) only in one ear or a noticeable difference in hearing between ears

(C) *Warning about pain from device placement.*--

WARNING: This hearing aid should not cause pain when inserting it.

Remove this device from your ear if it causes pain or discomfort when inserting or placing it. To try again, make sure to follow the instructions. If you feel pain or discomfort again, contact the manufacturer. You may also report this to FDA as an adverse event according to the instructions that appear later.

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(ii) Any additional warnings the manufacturer may include prior to the caution and notices to users in paragraph (c)(2)(iii) of this section.

(iii) The following caution and notices for users, which shall appear prior to any content except the cover page and the warnings under paragraphs (c)(2)(i) and (ii) of this section:

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(A) *Caution about hearing protection.*--

Caution: This is not hearing protection.

You should remove this device if you experience overly loud sounds, either of short or long duration. You should use appropriate hearing protection in loud environments. As a general rule, if you would use ear plugs in a loud environment, you should remove this device and use ear plugs in that environment.

(B) *Caution about excessive sound output.*--

Caution: The sound output should not be uncomfortable or painful.

You should turn down the volume or remove the device if the sound output is uncomfortably loud or painful.

(C) *Advice to seek professional services.*--

Note: If you remain concerned, consult a professional.

If you try this device and continue to struggle with or remain concerned about your hearing, you should consult with a hearing healthcare professional.

(D) *Note about user expectations.*--

Note: Expectations about what a hearing aid can do

A hearing aid will not restore normal hearing and may not completely eliminate difficulty hearing over noise. Further, a hearing aid will not prevent or improve a hearing impairment resulting from a medical condition(s).

For many people, the use of a hearing aid may be more satisfactory with training or counseling because the device is only one part of hearing habilitation.

Also, if you have hearing loss in both ears, use of hearing aids for both ears (bilateral hearing aids) may provide more benefit than just one hearing aid, especially in demanding listening situations—for example, noisy environments.

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(E) *Note about reporting adverse events to FDA.*--

Note: Tell FDA about injuries, malfunctions, or other adverse events.

To report an adverse event, you should submit the information to FDA as soon as possible after the event. Adverse events can include: ear canal or outer ear skin irritation, injury from the device (like cuts or scratches, or burns from an overheated battery), pieces of the device lodged in your ear canal, sudden increased severity in hearing loss with device use, etc.

Instructions for reporting are available at https://www.fda.gov/Safety/MedWatch, or call 1-800-FDA-1088.

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(iv) An illustration(s) of the OTC hearing aid that indicates operating controls, user adjustments, and the battery compartment.

(v) Information on the function of all controls intended for user adjustment.

(vi) A description of any accessory that accompanies the OTC hearing aid, including but not limited to wax guards and accessories for use with a computer, television, or telephone.

(vii) Specific instructions for all of the following:

(A) Instructions for sizing or inserting the eartip of the OTC hearing aid to prevent insertion past the bony-cartilaginous junction of the external auditory canal and damage to the tympanic membrane.

(B) The tools, tests, or software that allow the user to control the OTC hearing aid, including self-select, self-fit, and self-check the performance of the OTC hearing aid, and customize it to the user's hearing needs, including information about properly fitting eartips.

(C) Use of the OTC hearing aid with any accompanying accessories.

(D) Maintenance and care of the OTC hearing aid, including the procedure to follow in washing the earmold, when replacing tubing on those hearing aids that use tubing, and in storing the hearing aid when it will not be used for an extended period of time.

(E) If the battery is replaceable or rechargeable, how to replace or recharge the battery, including a generic designation of replacement batteries.

(F) Expected battery life.

(G) Any other information necessary for adequate directions for use as defined in § 801.5.

(viii) Identification of any known physiological side effects associated with the use of the OTC hearing aid that may warrant consultation with a physician, including if applicable, skin irritation and accelerated accumulation of cerumen (ear wax).

(ix) The technical specifications required by paragraph (c)(4) of this section.

(x) A description of commonly occurring, avoidable events that could adversely affect or damage the OTC hearing aid, including but not limited to ear wax buildup, drops, immersion in water, or exposure to excessive heat.

(xi) If the hearing aid incorporates wireless technology in its programming or use, appropriate warnings, instructions, and information relating to electromagnetic compatibility and wireless technology and human exposure to non-ionizing radiation.

(xii) If the manufacturer provides a repair service or licenses or certifies third-party repair services, information on how and where to obtain repair service, including at least one specific address where the user can go or send the OTC hearing aid to obtain such repair service.

(xiii) If clinical or non-clinical studies were conducted by or for the manufacturer to support the performance of the OTC hearing aid, a summary of all such studies.

(3) *Labeling on the device.* The labeling on an OTC hearing aid itself shall bear all of the following clearly and permanently, except as provided in paragraph (c)(3)(iii) of this section:

(i) The serial number.

(ii) If the battery is removable, a “+” symbol to indicate the positive terminal for battery insertion unless the battery's physical design prevents inserting the battery in the reversed position.

(iii) If the OTC hearing aid is used or rebuilt, the manufacturer shall physically attach a removable tag to the hearing aid declaring that fact.

(4) *Technical specifications.* All of the following technical specifications shall appear in the user instructional brochure that accompanies the device. You may additionally include it on the outside package.

(i) The maximum output limit value (OSPL90).

(ii) The full-on gain value, which is the gain with a 50 dB SPL pure-tone input and volume set to full on.

(iii) The total harmonic distortion value.

(iv) The self-generated noise value.

(v) The latency value.

(vi) The upper and lower cutoff frequencies for bandwidth.

(d) *Output limits*. The output limit for an OTC hearing aid shall be the device maximum acoustic output sound pressure level (SPL) in a 2-cubic centimeter (cm^3) coupler when the device input is a 90 dB SPL pure-tone, and the gain/volume control is full on. An OTC hearing aid shall not exceed the following limits:

(1) *General output limit*. An OTC hearing aid shall not exceed an output limit of 115 dB SPL at any frequency except as provided in paragraph (d)(2) of this section.

(2) *Output limit for a device with input-controlled compression and user-adjustable volume control*. An OTC hearing aid that includes input-controlled compression and a user-adjustable volume control shall not exceed an output limit of 120 dB SPL at any frequency.

(e) *Electroacoustic performance limits*. An OTC hearing aid shall perform within all of the following electroacoustic limits. Measure each electroacoustic performance characteristic using a 2-cm^3 coupler where applicable.

(1) *Output distortion control limits*. Test the output distortion of the OTC hearing aid as follows to ensure that it does not exceed the limit specified in paragraphs (e)(1)(i) through (iii) of this section.

(i) The total harmonic distortion plus noise shall not exceed 5 percent for output levels within one of the following sets of levels, depending on the test method: 🗋

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(A) Using sine wave-based testing, measure at 70 dB SPL and 100 dB SPL; or

(B) Using a 500-Hz one-third-octave pulsed-noise signal, measure at 67 dB SPL and 97 dB SPL.

(ii) You must measure the total harmonic distortion using a 500-Hz input tone with an analyzer that has a bandwidth at least as wide as the frequency limits of the OTC hearing aid.

(iii) You must measure the output distortion at the OTC hearing aid's maximum volume and the input sound level to the OTC hearing aid adjusted to produce the required outputs.

(2) *Self-generated noise level limits*. Self-generated noise shall not exceed 32 dB SPL. You must disable any methods that artificially lower the apparent noise floor for the measurement. Such methods would include but are not limited to auto-muting and downward expansion.

(3) *Latency*. Latency shall not exceed 15 ms. You must measure the latency with a method that is accurate and repeatable to within 1.5 ms.

(4) *Frequency response bandwidth*. The lower cutoff frequency shall extend to 250 Hz or below, and the upper cutoff frequency shall extend to 5 kHz or greater. You must measure the frequency response bandwidth as specified in the Method for clause 4.1 in ANSI/CTA-2051:2017.

(5) *Frequency response smoothness*. No single peak in the one-third-octave frequency response shall exceed 12 dB relative to the average levels of the one-third-octave bands, two-thirds octave above and below the peak. You must measure the frequency response smoothness using values for a diffuse field and the corrected one-third-octave frequency insertion response as specified in the Method for clause 4.1 in ANSI/CTA-2051:2017.

(f) *Design requirements*. An OTC hearing aid must conform to all of the following design requirements.

(1) *Insertion depth*. The design of an OTC hearing aid shall limit the insertion of the eartip to the bony-cartilaginous junction of the external auditory canal and no deeper.

(2) *Use of atraumatic materials*. The material for the eartip of an OTC hearing aid shall be atraumatic.

(3) *Proper physical fit*. The OTC hearing aid shall be designed to enable consumers to readily achieve a safe, customized, acoustically favorable, and comfortable physical fit in the ear canal and/or external ear.

(4) *Tools, tests, or software*. The OTC hearing aid shall, through tools, tests, or software, permit a lay user to control the device and customize it to the user's hearing needs.

(g) *Condition for sale of an OTC hearing aid*. The sale of an OTC hearing aid to or for a person younger than 18 years of age is prohibited.

(h) *Effect on State law*. Any State or local government requirement for an OTC hearing aid is preempted to the following extent.

(1) *Preemption*. No State or local government shall establish or continue in effect any law, regulation, order, or other requirement specifically related to hearing products that would restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of OTC hearing aids through in-person transactions, by mail, or online, that is different from, in addition to, or otherwise not identical to, the regulations issued under section 709(b) of the FDA Reauthorization Act of 2017, including any State or local requirement for the supervision, prescription, or other order, involvement, or intervention of a licensed person for consumers to access OTC hearing aids.

(2) *Professional requirements*. —(A) *General rule*. The servicing, marketing, sale, dispensing, customer support, or distribution of OTC hearing aids, or an equivalent activity, whether through in-person transactions, by mail, or online, shall not cause, require, or otherwise obligate a person providing such services to obtain specialized licensing, certification, or any other State or local sanction unless such requirement is generally applicable to the sale of any product or to all places of business regardless of whether they sell OTC hearing aids. However, although a State or local government may not require the order, involvement, or intervention of a licensed person for consumers to access OTC hearing aids, a licensed person may service, market, sell, dispense, provide customer support for, or distribute OTC hearing aids.

(B) *Sale of OTC hearing aids is not an exemption*. The servicing, marketing, sale, dispensing, customer support, or distribution of OTC hearing aids does not exempt a person from any State or local government's professional or establishment requirements that are consistent with this section.

(C) *Representations may create professional obligations.* A person shall not incur specialized obligations by representing as a servicer, marketer, seller, dispenser, customer support representative, or distributor (or an equivalent description) of OTC hearing aids. However, a person representing as any other defined professional or establishment, or as a State licensed dispenser, is subject to applicable State and local requirements even if the person undertakes commercial or professional activities only in relation to OTC hearing aids.

(3) *Private remedies.* This section does not modify or otherwise affect the ability of any person to exercise a private right of action under any State or Federal product liability, tort, warranty, contract, or consumer protection law.

(i) *Incorporation by reference.* (A) The standard required in this section is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552 (https://www.govinfo.gov/link/uscode/5/552?type=usc&year=mostrecent&link-type=html) (a) and 1 CFR part 51 (/select-citation/2021/10/20/1-CFR-51). All approved material is available for inspection at the Food and Drug Administration, Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, and is available from the sources indicated below. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov (mailto:fr.inspection@nara.gov)* or go to *https://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html (https://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html)* .

(B) *ANSI.* The American National Standards Institute, 1889 L Street NW, 11th floor, Washington, DC 20036, *storemanager@ansi.org (mailto:storemanager@ansi.org), https://www.ansi.org (https://www.ansi.org),* 202-293-8020.

(*1*) ANSI/CTA-2051, “Personal Sound Amplification Performance Criteria,” clause 4.1, dated January 2017.

(*2*) [Reserved]

(ii) [Reserved]

PART 801—LABELING

3. The authority citation for part 801 is revised to read as follows:

Authority: 21 U.S.C. 321 (https://www.govinfo.gov/link/uscode/21/321?type=usc&year=mostrecent&link-type=html), 331-334, 351, 352, 360d, 360i, 360j, 371, 374.

§ 801.420 [Removed]

4. Remove § 801.420.

§ 801.421 [Removed]

5. Remove § 801.421.

6. Add § 801.422 to subpart H to read as follows:

§ 801.422 Prescription hearing aid labeling.

(a) *Scope.* This section specifies the labeling requirements for prescription hearing aids. Any hearing aid that does not satisfy the requirements of § 800.30 of this chapter shall be a prescription device. Unless otherwise specified, the requirements in this section are in addition to

other applicable requirements, including but not limited to special controls found in the applicable classification regulation. This section does not apply to group auditory trainers.

(b) *Definitions for the purposes of this section*. This section uses the following definitions:

Dispenser. A dispenser is any person, as defined in section 201(e) of the Federal Food, Drug, and Cosmetic Act, engaged in the sale of prescription hearing aids to any member of the consuming public or any employee, agent, salesperson, and/or representative of such a person.

Hearing aid. A hearing aid is any wearable device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing.

Prescription hearing aid. A prescription hearing aid is a hearing aid that is not an over-the-counter (OTC) hearing aid as defined in § 800.30 of this chapter or a hearing aid that does not satisfy the requirements in § 800.30 of this chapter.

Sale. Sale includes a lease, rental, or any other purchase or exchange for value.

Used hearing aid. A hearing aid is "used" if a user has worn it for any period of time. However, a hearing aid shall not be "used" merely because a prospective user wore it as part of a bona fide hearing aid evaluation to determine whether to select that particular hearing aid for that prospective user. A hearing aid evaluation is "bona fide" if it was conducted in the presence of the dispenser or a hearing health professional selected by the dispenser to assist the prospective user in making a determination.

(c) *Labeling*. A prescription hearing aid shall bear all of the following labeling.

(1) *Outside package labeling*. The outside package of a prescription hearing aid shall bear all of the following:

(i) *Warnings*. All of the following shall appear on the outside package:

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(A) *Warning against use in people younger than 18 without prior medical evaluation.*--

WARNING – Medical evaluation for people younger than 18: The use of a hearing aid in people younger than 18 years old without a medical evaluation may worsen impairment or disability. A prospective hearing aid user who is younger than 18 should have a recent medical evaluation from a licensed physician, preferably an ear specialist. Prior to purchase, a physician should determine that the person is a candidate for the use of a hearing aid.

(B) *"Red flag" conditions.*--

WARNING: Conditions that Require Medical Care

Prior to purchasing this device, you should promptly consult with a licensed physician, preferably an ear specialist, if you have any of the following:

- Visible deformity of the ear, either present since birth or from trauma
- Fluid, pus, or blood coming out of the ear in the past 6 months
- Pain or discomfort in the ear
- History of excessive ear wax or suspicion that something is in the ear canal
- Episodes of vertigo (a sensation of spinning or swaying) or severe dizziness
- Sudden, quickly worsening, or fluctuating hearing loss in the past 6 months
- Hearing loss or ringing (tinnitus) only in one ear or a noticeable difference in hearing between ears

(ii) *Notices.* All of the following shall appear on the outside package:

(A) *Note about device trial options.*--

Note: Ask about trial-rental or purchase-option programs.

If you are unsure about your ability to adapt to using a hearing aid, you should ask about the availability of a trial-rental or purchase-option program. Many hearing aid dispensers offer programs that allow you to wear a hearing aid for a period of time for a nominal fee after which you may decide if you want to purchase the hearing aid.

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(B) *Statement of build condition.* If the prescription hearing aid is used or rebuilt, the outside package shall declare that fact. A sticker under and visible through the outer wrapper will suffice to declare such fact.

(2) *Labeling, inside the package.* The manufacturer or distributor of a prescription hearing aid shall include a user instructional brochure inside the package and shall make an electronic version available for download without site or customer registration and without requiring purchase of any product or service. The user instructional brochure shall include all of the following:

(i) The following warnings, which shall appear in the following order and prior to any content except the cover page:

(A) *Warning against use in people younger than 18 without prior medical evaluation.*--

WARNING – Medical evaluation for people younger than 18: The use of a hearing aid in people younger than 18 years old without a medical evaluation may worsen impairment or disability. A prospective hearing aid user who is younger than 18 should have a recent medical evaluation from a licensed physician, preferably an ear specialist. Prior to purchase, a physician should determine that the person is a candidate for the use of a hearing aid.

(B) *"Red flag" conditions, addressed to dispensers.*--

WARNING to Hearing Aid Dispensers:

You should advise a prospective hearing aid user to consult promptly with a licensed physician, preferably an ear specialist, before dispensing a hearing aid if you determine through inquiry, actual observation, or review of any other available information concerning the prospective user, that the prospective user has any of the following:

- Visible deformity of the ear, either congenital or traumatic
- Fluid, pus, or blood coming out of the ear in the past 6 months
- Pain or discomfort in the ear
- History of excessive ear wax or suspicion that something is in the ear canal
- Episodic vertigo or severe dizziness
- Sudden, quickly worsening, or fluctuating hearing loss in the past 6 months
- Hearing loss or ringing (tinnitus) only in one ear or a noticeable difference in hearing between ears
- Audiometric air-bone gap equal to or greater than 15 dB at 500 Hz, 1000 Hz, and 2000 Hz

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(C) *Warning to dispensers about very high-output devices.*--

WARNING to Hearing Aid Dispensers, Outputs in excess of 132 dB SPL:

You should exercise special care in selecting and fitting a hearing aid with a maximum output that exceeds 132 dB SPL because it may impair the remaining hearing of the hearing aid user.

(ii) The following caution and notices for users, which shall appear prior to any content, except the cover page and the warnings under paragraph (c)(2)(i) of this section:

(A) *Caution about hearing protection.*--

Caution: This is not hearing protection.

You should remove this device if you experience overly loud sounds, either of short or long duration. You should use appropriate hearing protection in loud environments. As a general rule, if you would use ear plugs in a loud environment, you should remove this device and use ear plugs in that environment.

(B) *Caution about excessive sound output.*--

Caution: The sound output should not be uncomfortable or painful.

You should turn down the volume or remove the device if the sound output is uncomfortably loud or painful.

(C) *Note about user expectations.*--

Note: Expectations about what a hearing aid can do

A hearing aid will not restore normal hearing and may not completely eliminate difficulty hearing over noise. Further, a hearing aid will not prevent or improve a hearing impairment resulting from a medical condition(s).

For many people, the use of a hearing aid may be more satisfactory with training or counseling because the device is only one part of hearing habilitation.

Also, if you have hearing loss in both ears, use of hearing aids for both ears (bilateral hearing aids) may provide more benefit than just one hearing aid, especially in demanding listening situations—for example, noisy environments.

(D) *Note about reporting adverse events to FDA.*--

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Note: Tell FDA about injuries, malfunctions, or other adverse events.

To report an adverse event, you should submit the information to FDA as soon as possible after the event. Adverse events can include: ear canal or outer ear skin irritation, injury from the device (like cuts or scratches, or burns from an overheated battery), pieces of the device lodged in your ear canal, sudden increased severity in hearing loss with device use, etc.

Instructions for reporting are available at https://www.fda.gov/Safety/MedWatch, or call 1-800-FDA-1088.

(E) *Note about hearing loss in people younger than 18 and fitting devices.*--

Note: Hearing loss in people younger than 18

- If you're younger than 18, you should see a doctor first, preferably an ear specialist.
- The doctor will identify and treat medical conditions when appropriate.
- The doctor may refer you to an audiologist for a separate test, a hearing aid evaluation.
- The hearing aid evaluation will help the audiologist select and fit the right hearing aid.

A person who is younger than 18 years old with hearing loss should have a medical evaluation by a licensed physician, preferably an ear specialist, before the purchase of a hearing aid. Licensed physicians who specialize in the ear are often called otolaryngologists, otologists, or otorhinolaryngologists. The purpose of a medical evaluation is to identify and treat all medical conditions that may affect hearing before the hearing aid is purchased for the person.

Following the medical evaluation and if appropriate, the physician will provide a written statement that the hearing loss has been medically evaluated and the person is a candidate for a hearing aid. The physician may refer you to an audiologist for a hearing aid evaluation, which is different from the medical evaluation and is intended to identify the appropriate hearing aid.

The audiologist will conduct a hearing aid evaluation to assess the hearing aid candidate's ability to hear with and without a hearing aid. The hearing aid evaluation will enable the audiologist to select and fit a hearing aid to the person's individual needs. An audiologist can also provide evaluation and rehabilitation since, for people younger than 18, hearing loss may cause problems in language development and educational and social growth. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of hearing loss in people younger than 18.

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(iii) An illustration(s) of the prescription hearing aid that indicates operating controls, user adjustments, and the battery compartment. 🗋

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(iv) Information on the function of all controls intended for user adjustment.

(v) A description of any accessory that accompanies the prescription hearing aid, including but not limited to wax guards, and accessories for use with a computer, television, or telephone.

(vi) Specific instructions for all of the following:

(A) Use of the prescription hearing aid with any accompanying accessories.

(B) Maintenance and care of the prescription hearing aid, including the procedure to follow in washing the earmold, when replacing tubing on those hearing aids that use tubing, and in storing the hearing aid when it will not be used for an extended period of time.

(C) If the battery is replaceable or rechargeable, how to replace or recharge the battery, including a generic designation of replacement batteries.

(D) Expected battery life.

(vii) Identification of any known physiological side effects associated with the use of the prescription hearing aid that may warrant consultation with a physician, including if applicable, skin irritation and accelerated accumulation of cerumen (ear wax).

(viii) The technical specifications required by paragraph (c)(4) of this section unless such specifications appear in separate labeling accompanying the prescription hearing aid.

(ix) A description of commonly occurring, avoidable events that could adversely affect or damage the prescription hearing aid, including but not limited to ear wax buildup, drops, immersion in water, or exposure to excessive heat.

(x) If the hearing aid incorporates wireless technology in its programming or use, appropriate warnings, instructions, and information relating to electromagnetic compatibility and wireless technology and human exposure to non-ionizing radiation.

(xi) If the manufacturer provides a repair service or licenses or certifies third-party repair services, information on how and where to obtain repair service, including at least one specific address where the user can go or send the prescription hearing aid to obtain such repair service.

(xii) If clinical or non-clinical studies were conducted by or for the manufacturer to support the performance of the prescription hearing aid, a summary of all such studies.

(3) *Labeling on the device.* The labeling on a prescription hearing aid itself shall bear all of the following clearly and permanently, except as provided in paragraph (c)(3)(iii) of this section:

(i) The serial number.

(ii) If the battery is removable, a "+" symbol to indicate the positive terminal for battery insertion unless the battery's physical design prevents inserting the battery in the reversed position.

(iii) If the prescription hearing aid is used or rebuilt, the manufacturer shall physically attach a removable tag to the hearing aid declaring that fact.

(4) *Technical specifications.* Technical specifications useful in selecting, fitting, and checking the performance of the prescription hearing aid shall appear in the user instructional brochure or in separate labeling that accompanies the device. You must determine the technical specification values for the prescription hearing aid labeling in accordance with the test procedures of the American National Standard, "Specification of Hearing Aid Characteristics," ANSI/ASA S3.22-2014. As a minimum, the user instructional brochure or such other labeling shall include the appropriate values or information for the following technical specification elements as these elements are defined or used in such standard:

(i) Saturation output curve (SSPL 90 curve).

(ii) Frequency response curve.

(iii) Average saturation output (HF-Average SSPL 90).

(iv) Average full-on gain (HF-Average full-on gain).

(v) Reference test gain.

(vi) Frequency range.

(vii) Total harmonic distortion.

(viii) Equivalent input noise.

(ix) Battery current drain.

(x) Induction coil sensitivity (telephone coil aids only).

(xi) Input-output curve (only for hearing aids with automatic gain control).

(xii) Attack and release times (only for hearing aids with automatic gain control).

(5) *Misbranding*. A prescription hearing aid that is not labeled as required under this section and § 801.109 of this chapter shall be misbranded under sections 201(n), 502(a), and/or 502(f) of the Federal Food, Drug, and Cosmetic Act.

(d) *Incorporation by reference.* (1) The standard required in this section is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552 (https://www.govinfo.gov/link/uscode/5/552?type=usc&year=mostrecent&link-type=html) (a) and 1 CFR part 51 (/select-citation/2021/10/20/1-CFR-51). All approved material is available for inspection at the Food and Drug Administration, Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, and is available from the sources indicated below. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov (mailto:fr.inspection@nara.gov)* or go to *https://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html (https://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).:*

(2) *ANSI*. The American National Standards Institute, 1889 L Street NW, 11th Floor, Washington, DC 20036, *storemanager@ansi.org (mailto:storemanager@ansi.org), https://www.ansi.org (https://www.ansi.org),* 202-293-8020.

(i) ANSI/ASA S3.22-2014, "Specification of Hearing Aid Characteristics," dated November 2014.

(ii) [Reserved]

PART 808—EXEMPTIONS FROM FEDERAL PREEMPTION OF STATE AND LOCAL MEDICAL DEVICE REQUIREMENTS

7. The authority citation for part 808 is revised to read as follows:

Authority: 21 U.S.C. 360 (https://www.govinfo.gov/link/uscode/21/360?type=usc&year=mostrecent&link-type=html)j, 360k, 371.

Section 808.1 also issued under Sec. 709, Pub. L. 115-52 (https://www.govinfo.gov/link/plaw/115/public/52?link-type=html), 131 Stat. 1065-67.

PART 808—[AMENDED]

8. In part 808, remove the words "the act" and add in their place "the Federal Food, Drug, and Cosmetic Act".

9. In § 808.1, add headings to paragraphs (a) through (f) and add paragraph (g) to read as follows:

§ 808.1 Scope.

(a) *Introduction.* * * *

(b) *General rule for State and local requirements respecting devices.* * * *

(c) *Exempting from preemption certain State or local requirements respecting devices.* * * *

(d) *Meaning of "requirements applicable to a device."* * * *

(e) *Determination of equivalence or difference of requirements applicable to a device.* * * *

(f) *Applicability of Federal requirements respecting devices.* * * *

(g) *Exemptions not applicable to certain State or local government requirements specifically related to hearing products.* An exemption under this part shall not apply to any State or local government law, regulation, order, or other requirement specifically related to hearing products, including any requirement for the supervision, prescription, or other order, involvement, or intervention of a licensed person for consumers to access over-the-counter hearing aids, that:

(1) Would restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of over-the-counter hearing aids, as defined under section 520(q) of the Federal Food, Drug, and Cosmetic Act, through in-person transactions, by mail, or online; and

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(2) Is different from, in addition to, or otherwise not identical to, the regulations issued under section 709(b) of the FDA Reauthorization Act of 2017.

10. Revise § 808.3 to read as follows:

§ 808.3 Definitions.

Compelling local conditions includes any factors, considerations, or circumstances prevailing in, or characteristic of, the geographic area or population of the State or political subdivision that justify exemption from preemption.

More stringent refers to a requirement of greater restrictiveness or one that is expected to afford to those who may be exposed to a risk of injury from a device a higher degree of protection than is afforded by a requirement applicable to the device under the Federal Food, Drug, and Cosmetic Act.

Political subdivision or *locality* means any lawfully established local governmental unit within a State which unit has the authority to establish or continue in effect any requirement having the force and effect of law with respect to a device intended for human use.

State means any State or Territory of the United States, including but not limited to, the District of Columbia and the Commonwealth of Puerto Rico.

Substantially identical to refers to the fact that a State or local requirement does not significantly differ in effect from a Federal requirement.

§ 808.53 [Removed and Reserved]

11. Remove and reserve § 808.53.

12. Revise § 808.55 to read as follows:

§ 808.55 California.

The following California medical device requirements are preempted under section 521(a) of the Federal Food, Drug, and Cosmetic Act, and FDA has denied them exemption from preemption:

(a) *Medical devices; general provisions.* Sherman Food, Drug, and Cosmetic Law, Division 21 of the California Health and Safety Code, sections 26207, 26607, 26614, 26615, 26618, 26631, 26640, and 26441, to the extent that they apply to devices; and

(b) *Ophthalmic devices; quality standards.* California Business and Professions Code, section 2541.3 to the extent that it requires adoption of the American National Standards Institute standards Z-80.1 and Z-80.2.

§§ 808.57 through 808.101 [Removed and Reserved]

13. Remove and reserve §§ 808.57 through 808.101.

PART 874—EAR, NOSE, AND THROAT DEVICES

14. The authority citation for part 874 continues to read as follows:

Authority: 21 U.S.C. 351 (https://www.govinfo.gov/link/uscode/21/351?type=usc&year=mostrecent&link-type=html), 360, 360c, 360e, 360j, 360l, 371.

15. Redesignate § 874.3300 as § 874.3301 and revise to read as follows:

§ 874.3301 Bone-conduction hearing aid.

(a) *Identification.* A bone-conduction hearing aid is a wearable sound-amplifying device intended to compensate for impaired hearing and that transmits sound to the inner ear through the skull. A bone-conduction hearing aid is subject to the requirements in § 801.422 of this chapter.

(b) *Classification.* Class II.

16. Revise § 874.3305 to read as follows:

§ 874.3305 Air-conduction hearing aid.

(a) *Identification.* An air-conduction hearing aid is a wearable sound-amplifying device intended to compensate for impaired hearing that conducts sound to the ear through the air. An air-conduction hearing aid may be wireless, self-fitting, or both. An air-conduction hearing aid is subject to the requirements in § 800.30 or § 801.422 of this chapter, as applicable. Air-conduction hearing aid generic types exclude the group hearing aid or group auditory trainer, master hearing aid, and the tinnitus masker, regulated under §§ 874.3320, 874.3330, and 874.3400, respectively.

(b) *Classification.* (1) *Legacy hearing aid.* Class I for an air-conduction hearing aid that is not a wireless or self-fitting device. This hearing aid is exempt from premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

(2) *Wireless hearing aid.* Class II (special controls) for an air-conduction hearing aid that incorporates wireless technology in its programming or use. A wireless hearing aid may also be a self-fitting hearing aid. A wireless hearing aid that is not a self-fitting hearing aid is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9. The special controls for a wireless hearing aid are:

(i) Performance data must demonstrate the electromagnetic compatibility (EMC), electrical safety, and thermal safety of the device;

(ii) Performance testing must validate safety of exposure to non-ionizing radiation; and

(iii) Performance data must validate wireless technology functions.

(3) *Self-fitting hearing aid.* Class II (special controls) for a wireless air-conduction hearing aid that incorporates technology, including software, that allows users to program their hearing aids. This technology integrates user input with a self-fitting strategy and enables users to independently derive and customize their hearing aid fittings and settings. A self-fitting hearing aid is not exempt from premarket notification procedures, notwithstanding the exemption in paragraph (b)(2) of this section. The special controls for a self-fitting hearing aid, in addition to the special controls for a wireless hearing aid if the device incorporates wireless technology, are:

(i) Clinical data must evaluate the effectiveness of the self-fitting strategy;

(ii) Electroacoustic parameters, including maximum output limits, distortion levels, self-generated noise levels, latency, and frequency response, must be specified and tested;

(iii) Software verification, validation, and hazard analysis must be performed; and

(iv) Usability testing must demonstrate that users can correctly use the device as intended under anticipated conditions of use.

17. In § 874.3315, revise paragraph (a) to read as follows:

§ 874.3315 Tympanic membrane contact hearing aid.

(a) *Identification.* A tympanic membrane contact hearing aid is a prescription wearable device that compensates for impaired hearing. Amplified sound is transmitted by vibrating the tympanic membrane through a transducer that is in direct contact with the tympanic membrane. A tympanic membrane contact hearing aid is subject to the requirements in § 801.422 of this chapter.

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§ 874.3325 [Removed]

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18. Remove § 874.3325.

19. In § 874.3950, add a sentence at the end of paragraph (a) to read as follows:

§ 874.3950 Transcutaneous air conduction hearing aid system.

(a) * * * A transcutaneous air conduction hearing aid system is subject to the requirements in § 801.422 of this chapter.

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Dated: October 8, 2021.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

Footnotes

1. "Device type" as used in this document has the same meaning as "generic type of device" in 21 CFR 860.3 (/select-citation/2021/10/20/21-CFR-860.3)(i) (a "generic type of device" means "a grouping of devices that do not differ significantly in purpose, design, materials, energy source, function, or any other feature

related to safety and effectiveness, and for which similar regulatory controls are sufficient to provide reasonable assurance of safety and effectiveness").
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2. We use the term "non-prescription" because the FD&C Act, as amended by FDARA, defines OTC hearing aids and requires FDA to undertake rulemaking to establish the OTC category. As such, no hearing aid is yet OTC within the meaning of section 520(q) of the FD&C Act. We use "non-prescription" to avoid confusing the intended uses of current devices with devices that would eventually meet the OTC Hearing Aid Controls.
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3. Additionally, FDARA section 709(b)(5) addresses the effect of section 709 on certain private remedies.
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4. Section 520(q)(1)(B) of the FD&C Act also specifically excludes from the definition of OTC hearing aids products intended to amplify sound for nonhearing impaired consumers in situations including hunting and bird watching.
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5. Although some have suggested the use of a different name for OTC hearing aids, for example, a "wearable," we are proposing to continue referring to them as hearing aids to maintain consistency with the device type classifications and section 520(q) of the FD&C Act.
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6. See section III.G, discussing the codification of the preemption provision, section 709(b)(4) of FDARA.
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7. OSPL90 is an abbreviation for the sound output as measured in a standardized way. ANSI/ASA S3.22-2014 defines it as the SPL developed in the specified 2-cm3. earphone coupler when the input SPL is 90 dB with the gain control of the hearing aid full-on. To simplify, this describes a way to simulate amplifying a sound into the ear canal, providing a standardized measurement for the amplified output.
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8. Weighting sound levels means that different frequency ranges have different values (weights) added or subtracted to them, so for example, lower frequencies may receive more weight than higher frequencies for the purpose of expressing the sound level. Different sets of weighting values have different purposes. A-weighting tries to account for the fact that the human ear is less sensitive to lower frequencies, which generally do not sound as loud to people as higher frequencies at the same SPL. Therefore, A-weighted decibels can be useful to express how a listener might perceive a sound level when considering the ear's variable sensitivity to different frequencies. This weighting method is common but is not the only one that accounts for human hearing perception. C-weighting is another.
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9. Based on the 3-dB exchange rate—above 85 dB SPL, the time halves for each 3-dB increase—of Clause 1.1.1 of NIOSH-98, which is used by ANSI/CTA-2051, exposure to 115 dB SPL is $2^{(5/3)}$ or 3.17 times the ANSI/CTA-2051 recommended exposure limit of 28 seconds for 120 dB SPL, equaling approximately 89 seconds.
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10. Note that the consensus standard includes a maximum acoustic output as a Category 1 specification; however, we are proposing a different maximum output level rather than the consensus standard's (see section III.D). Additionally, we are proposing a latency limit, which the standard includes as a Category 2 specification.
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11. We refer to hearing products more generally, not just OTC hearing aids. We wish to make clear that a State or locality may not establish requirements for hearing products if those requirements would restrict or interfere with commercial activity involving OTC hearing aids. However, we do not interpret section 709 of FDARA as preempting requirements that apply only to prescription hearing aids (provided they do not restrict or interfere with commercial activity involving OTC hearing aids) but such requirements could be preempted under section 521 of the FD&C Act.
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PUBLISHED DOCUMENT

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request:	2) Date When Request Submitted:
Katie Schmidt	**12/1/2021** Items will be considered late if submitted after 4:30 p.m. and less than: ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others

3) Name of Board, Committee, Council, Sections:

Hearing and Speech Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
1/10/2022	☐ Yes ☒ No	**School/Medical Facility Caseload Discussion**

7) Place Item in:	8) Is an appearance before the Board being scheduled?	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session ☐ Both	☐ Yes (Fill out Board Appearance Request) ☒ No	

10) Describe the issue and action that should be addressed:

Board liaison Kathy Pazak has requested that the board discuss caseload size in schools and medical facilities for future recommendations to license holders.

11) Authorization

Kathleen Schmidt — *12/1/2021*

Signature of person making this request — **Date**

Samantha Lange — 12/2/2021

Supervisor (if required) — **Date**

Executive Director signature (indicates approval to add post agenda deadline item to agenda) **Date**

Directions for including supporting documents:
1. This form should be attached to any documents submitted to the agenda.
2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.
3. If necessary, Provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.