NOTIFICATION

Addendum

The following communication, dated 23 August 2022, is being circulated at the request of the delegation of the United States of America.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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

|  |  |
| --- | --- |
| **Reason for Addendum:** | |
| [ ] | Comment period changed - date: |
| [ ] | Notified measure adopted - date: |
| [X] | Notified measure published - date: 17 August 2022 |
| [X] | Notified measure enters into force - date: 17 October 2022 |
| [X] | Text of final measure available from[[1]](#footnote-1):  <https://www.govinfo.gov/content/pkg/FR-2022-08-17/html/2022-17230.htm>  <https://www.govinfo.gov/content/pkg/FR-2022-08-17/pdf/2022-17230.pdf>  <https://members.wto.org/crnattachments/2022/TBT/USA/final_measure/22_5728_00_e.pdf> |
| [ ] | Notified measure withdrawn or revoked - date:  Relevant symbol if measure re-notified: |
| [ ] | Content or scope of notified measure changed and text available from1:  New deadline for comments (if applicable): |
| [ ] | Interpretive guidance issued and text available from1: |
| [ ] | Other: |

**Description:** TITLE: Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS)

ACTION: Final rule

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is establishing a regulatory category for over-the-counter (OTC) hearing aids and making related amendments to update the regulatory framework for hearing aids. Specifically, we define OTC hearing aids and establish applicable requirements; amend existing rules for consistency with the 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 will become obsolete as a result of changes to the hearing aid requirements. 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: Effective date: This rule is effective 17 October 2022.

Compliance dates: For hearing aids that have been legally offered for sale prior to 17 October 2022, including hearing aids that already have a 510(k) clearance, compliance with the new or revised requirements must be achieved by 14 April 2023. For hearing aids that have not been offered for sale prior to 17 October 2022, or have been offered for sale but are required to submit a new 510(k) due to changes unrelated to this rule, 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 17 October 2022.

Incorporation by reference: The incorporation by reference of certain material listed in this rule is approved by the Director of the Federal Register as of 17 October 2022.

This final rule and the proposed rule notified as [G/TBT/N/USA/1791](https://docs.wto.org/imrd/directdoc.asp?DDFDocuments/t/G/TBTN21/USA1971.DOCX) are identified by Docket Number FDA-2021-N-0555. The Docket Folder is available on Regulations.gov at <https://www.regulations.gov/docket/FDA-2021-N-0555/document> and provides access to primary and supporting documents as well as comments received. Documents are also accessible from [Regulations.gov](http://www.regulations.gov/) by searching the Docket Number.

GUIDANCE DOCUMENT - Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products; Guidance for Industry and Food and Drug Administration Staff

AUGUST 2022: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-requirements-hearing-aid-devices-and-personal-sound-amplification-products>

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page at <https://www.fda.gov/media/87330/download>.

**\_\_\_\_\_\_\_\_\_\_**

1. This information can be provided by including a website address, a pdf attachment, or other information on where the text of the final/modified measure and/or interpretive guidance can be obtained. [↑](#footnote-ref-1)