

# WORLD TRADE ORGANIZATION

G/TBT/Notif.99/564  
17 November 1999

(99-5009)

## Committee on Technical Barriers to Trade

### NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

1.	<b>Member to Agreement notifying:</b> <u>UNITED STATES</u> <b>If applicable, name of local government involved (Articles 3.2 and 7.2):</b>
2.	<b>Agency responsible:</b> Food and Drug Administration (41) <b>Agency or authority designated to handle comments regarding the notification shall be indicated if different from above:</b>
3.	<b>Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:</b>
4.	<b>Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> Hearing Aids (HS Chapter 9021)
5.	<b>Title, number of pages and language(s) of the notified document:</b> Medical Devices; Hearing Aids; Technical Data Amendments (3 pages, in English)
6.	<b>Description of content:</b> The Administration is proposing to amend its regulations governing hearing aid labelling to reference the most recent version of the consensus standard used to determine the technical data to be included in labelling for hearing aids. This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the Federal Register.
7.	<b>Objective and rationale, including the nature of urgent problems where applicable:</b> To ensure that manufacturers may use state-of-the art methods to address technical data in hearing aid labelling.
8.	<b>Relevant documents:</b> 64 FR 59695, 3 November 1999; 21 CFR Part 801. Will appear in the Federal Register when adopted.
9.	<b>Proposed date of adoption:</b> To be determined <b>Proposed date of entry into force:</b>
10.	<b>Final date for comments:</b> 18 January 2000
11.	<b>Texts available from:</b> National enquiry point [X] or address, e-mail and telefax <b>number of the other body:</b> The text is also available on the Internet at: <a href="http://www.access.gpo.gov/nara/index.html">http://www.access.gpo.gov/nara/index.html</a>