

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Part 801

[Docket No. 99N-2550]

Medical Devices; Hearing Aids; Technical Data Amendments; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of March 17, 2000, for the final rule that appeared in the **Federal Register** of November 3, 1999 (64 FR 59618). The direct final rule amends regulations governing hearing aid labeling to reference the most recent version of the consensus standard used to determine technical data to be included in labeling for hearing aids. This amendment allows manufacturers to use state-of-the-art methods to address technical data in labeling for hearing aids. This document confirms the effective date of the direct final rule.

DATES: Effective date confirmed: March 17, 2000.

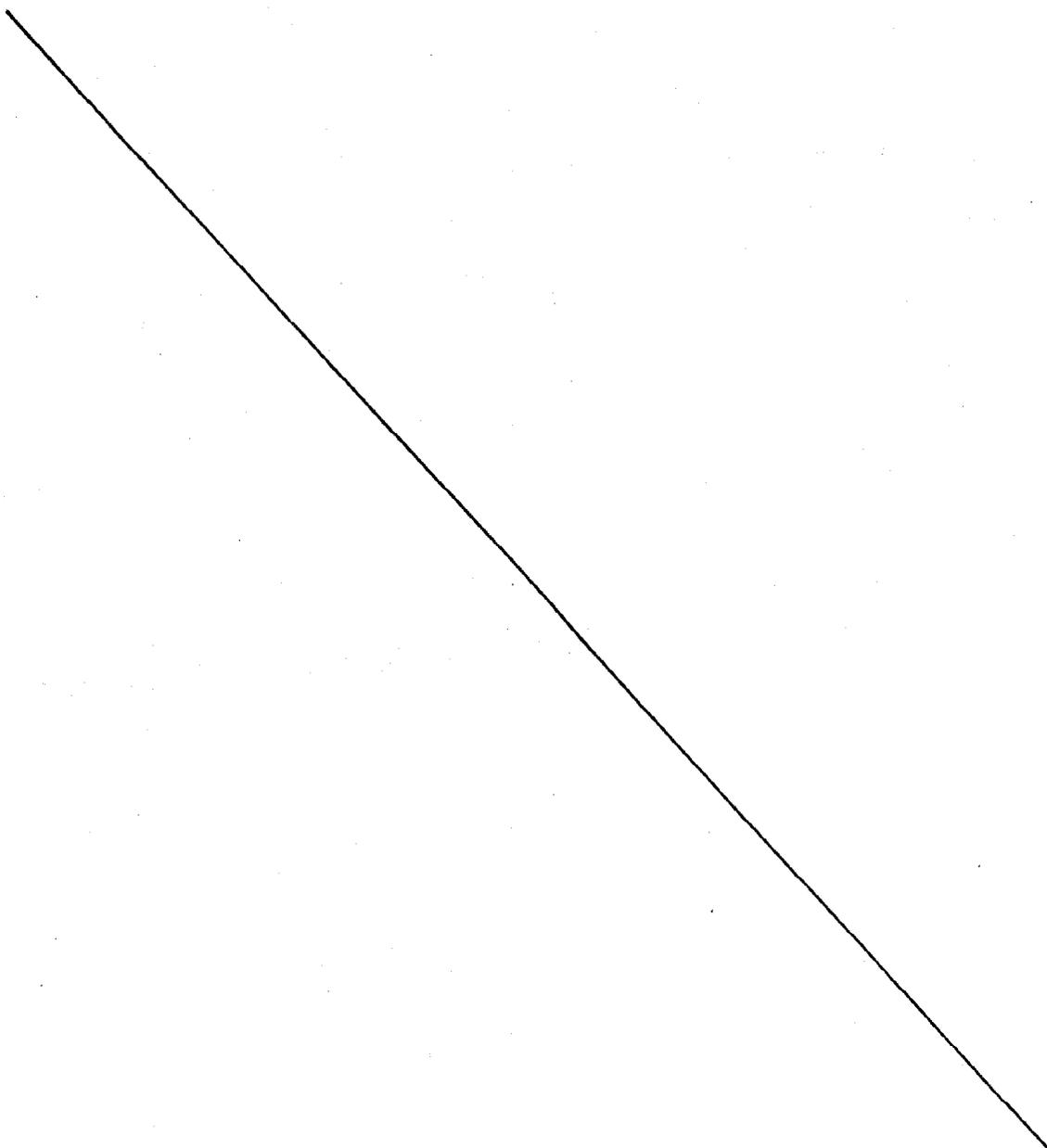
FOR FURTHER INFORMATION CONTACT: David A. Segerson, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2080.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 3, 1999 (64 FR 59618), FDA solicited comments concerning the direct final rule for a 75-day period ending January 17, 2000. FDA stated that the effective date of the direct final rule would be on March 17, 2000,

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60 days after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period. FDA did not receive any significant adverse comments.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, notice is given that no objections or requests for a hearing



were filed in response to the November 3, 1999, direct final rule. Accordingly, the amendments issued thereby are effective.

Dated: February 17, 2000



William K. Hubbard
Senior Associate Commissioner for Policy, Planning, and Legislation

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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