

**DEPARTMENT OF HEALTH AND  
HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 808**

[Docket No. 88P-0314]

**Exemption From Preemption of State  
and Local Hearing Aid Requirements;  
Vermont**

**AGENCY:** Food and Drug Administration,  
HHS.

**ACTION:** Proposed rule; notice of  
opportunity for hearing.

**SUMMARY:** The Food and Drug Administration (FDA), in response to an application from Vermont, is proposing that a Vermont statute concerning the sale of hearing aids be exempted from Federal preemption. The agency is also giving notice to interested persons of an opportunity to request an oral hearing on this proposal.

**DATES:** Written comments by December 31, 1990; requests for an oral hearing by November 29, 1990. FDA intends that if a final rule is issued based on this proposal, it shall be effective by November 29, 1990.

**ADDRESSES:** Written comments and requests for a hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 4-82, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ-84), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4874.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

On July 21, 1989, Vermont applied for exemption from Federal preemption under section 521 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360k) for 26 V.S.A. chapter 67, Section 3283a. This section states:

To the extent permitted by Federal law, no hearing aid may be sold to a person who does not own a hearing aid at the time of sale without a written statement signed by a licensed physician that states that the patient's hearing loss has been medically evaluated and the patient may be considered a candidate for a hearing aid. The medical evaluation must have taken place within the preceding six months.

**II. FDA Regulation**

The FDA regulation (21 CFR 801.421) prohibits a hearing aid dispenser from selling a hearing aid unless the prospective user has presented to the dispenser a statement signed by a licensed physician stating that the patient's hearing loss has been evaluated medically, and that the patient may be considered a candidate for a hearing aid. The medical evaluation must have taken place within the 6 months preceding the sale. An informed adult, 18 years of age or older, may waive the medical evaluation requirement by signing a written statement. The hearing aid dispenser is prohibited from actively encouraging the prospective user to waive the medical evaluation.

**III. Section 521 of the Act**

Section 521(a) of the act provides that no State or local government may establish or continue in effect any requirement with respect to the safety and effectiveness of a device or any other requirement applicable to the device under the act if such requirement is different from, or in addition to, a requirement which is applicable to the device under the act. Section 521(b) of the 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 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 act.

Under section 521(a) of the act, Vermont section 3283a is preempted because it is different from the FDA regulation in that it does not permit a waiver of the medical evaluation requirement for a first-time purchaser. Under section 521(b) of that act, the Vermont provision is eligible for exemption because it is more stringent than the FDA regulation.

**IV. Vermont Application**

Vermont is requesting exemption for section 3283a, because it believes that it is more stringent than the Federal requirements in that it has a more limited waiver provision and that it is required by compelling local conditions because FDA's waiver provision is widely abused in Vermont and its section 3283a would not cause hearing aids to be in violation of the Federal act. The Vermont application is supported

by data compiled by Vermont's Office of the Attorney General, which inspected the records of 10 Vermont hearing aid dispensers for sales records for the period of January 1986 to June 1988. These dispensers sold approximately 2,000 hearing aids during this period. (Some sales figures were estimated.)

The investigators inspected the records of 858 of these sales (33 percent). Of these 858 sales, 65 (7 percent) had physicians' statements, 642 (76 percent) had waiver statements, and 132 (15 percent) had neither. (FDA requires that these records be maintained for 3 years after the sale.) Vermont believes that these figures show that Vermont hearing aid dispensers are violating the spirit of the FDA regulations in that FDA states that it is not in the best interest of the purchaser to exercise the waiver.

**V. FDA's Evaluation**

In two separate documents published in the Federal Register of October 10, 1980 (45 FR 67325 and 67326), FDA issued a final rule responding to 21 applications for exemption from preemption for hearing aid requirements. At that time, FDA denied exemption from preemption for several State requirements similar to that for which Vermont now seeks exemption. FDA denied these applications, saying that, while it believed that a medical evaluation should be obtained, it also believed that an informed adult should be permitted to waive the medical evaluation requirement for religious and personal reasons. At that time, however, experience with the FDA regulation was somewhat limited and no State submitted information similar to that which Vermont has submitted. FDA now believes that Vermont has submitted sufficient information to grant an exemption.

States whose applications for exemption for similar requirements were denied in the past may apply again, if they can present documentation similar to that submitted by Vermont.

**VI. Effect of Exemption**

FDA emphasizes that, when it grants an exemption to a State or local requirement, the granting of the exemption does not in any manner affect FDA requirements under the act. FDA requirements continue in full force and effect regardless of whether comparable or related State or local requirements are preempted or exempted from preemption. For example, the Vermont statute applies only when a person does not own a

hearing aid at the time of sale: The FDA regulation will continue to apply whether or not the purchaser owns a hearing aid at the time of sale.

#### VII. Oral Hearing

Interested persons may on or before November 29, 1990, submit requests for an oral hearing to the Dockets Management Branch (address above). Two copies of any request should be submitted except that individuals may submit one copy. Requests should be identified with the docket number found in brackets in the heading of this document.

If the agency determines that an oral hearing should be held, it will announce the time, date, and place of the hearing in a Federal Register notice. The procedures that will govern any such hearing are those applicable to a public hearing before the Commissioner of Food and Drugs under part 15 (21 CFR part 15).

#### VIII. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### IX. Economic Impact

FDA has carefully analyzed the economic effects of this proposed rule and has determined that the proposed rule will not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act. In accordance with section 3(g)(1) of Executive Order 12291, the impact of this proposed rule has been carefully analyzed, and it has been determined that the proposed rule does not constitute a major rule as defined in section 1(b) of the Executive Order. Hearing aid dispensers are already required under the FDA rule to keep either a physician's statement or a waiver. Under the Vermont statute, they would be permitted to keep only a physician's statement in some cases. Therefore, no additional economic burden is being imposed on the dispensers. Using Vermont's figures, it is estimated that there are approximately 1,300 hearing aids sold in Vermont in a year. If each sale required a physician's evaluation and an evaluation cost \$100, the total yearly cost would be \$130,000. However, every sale does not require the physician's evaluation, as some sales are to persons who already own a hearing aid. There is no breakdown as

to how many sales would require the evaluation. Furthermore, there is an apparent cost savings attendant to a physician's evaluation in that many people cannot benefit from using a hearing aid and a physician is best positioned to make this determination. A hearing aid can cost in excess of \$400 and so the savings can be substantial. FDA invites further information on the costs that would be imposed by this proposal.

Interested persons may, on or before December 31, 1990, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

#### List of Subjects in 21 CFR Part 808

Intergovernmental relations, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 808 be amended as follows:

#### PART 808—EXEMPTIONS FROM FEDERAL PREEMPTION OF STATE AND LOCAL MEDICAL DEVICE REQUIREMENTS

1. The authority citation for 21 CFR part 808 continues to read as follows:

Authority: Secs. 521, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360k, 371).

2. Section 808.95 is added to Subpart C to read as follows:

#### § 808.95 Vermont.

The following Vermont medical device requirement is enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted it from preemption under section 521(b) of the act: 26 V.S.A., chapter 87, section 3283a, on the condition that it is enforced in addition to the applicable requirements of this chapter.

Dated: October 12, 1990.

Ronald G. Chesemore,  
Associate Commissioner for Regulatory Affairs.  
[FR Doc. 90-25603 Filed 10-29-90; 8:45 am]  
BILLING CODE 4160-01-M

#### DEPARTMENT OF LABOR

#### Occupational Safety and Health Administration

#### 29 CFR Part 1910

[Docket No. S-760-B]

RIN 1218-AB27

#### Accreditation of Training Programs for Hazardous Waste Operations

AGENCY: Occupational Safety and Health Administration, Labor.

ACTION: Proposed rule; cancellation and rescheduling of informal public hearing.

**SUMMARY:** On July 27, 1990, the Occupational Safety and Health Administration (OSHA) published a document in the Federal Register (55 FR 30720) scheduling informal public hearings to begin on October 2, 1990, and reopening the written comment period for its proposed rule on Accreditation of Training Programs for Hazardous Waste Operations published in the Federal Register January 26, 1990 (55 FR 2776). On September 14, 1990, OSHA published another notice in the Federal Register (55 FR 37902) that reopened the comment period, cancelled the October hearings and rescheduled the hearings to begin on February 5, 1991. It has become necessary for OSHA to change the week of hearings scheduled for February 5-8, 1991 to not take place January 29-February 1, 1991 in Washington, DC. The hearing scheduled for February 12-14, 1991 in Cincinnati, OH will be held as previously scheduled. The dates for submission of comments, notices of intention to appear and testimony remain unchanged.

**DATES:** 1. The informal public hearing for OSHA's Accreditation of Training Programs for Hazardous Waste Operations rulemaking scheduled for February 5, 1991 through February 8, 1991 in Washington, DC is cancelled and rescheduled to begin at 9:30 a.m. January 29, 1991 through February 1, 1991 in Washington, DC.

The hearing announced on September 14, 1990 (55 FR 37902) scheduled for February 12, 1991 through February 14, 1991 in Cincinnati, OH will be held as planned starting at 9:30 a.m.

2. Notices of intention to appear must be postmarked by December 17, 1990. Written comments, testimony and all other evidence which will be offered into the hearing record must be postmarked by January 21, 1991.

**ADDRESSES:** 1. Four copies of the notice of intention to appear, testimony, and documentary evidence which will be introduced into the hearing record must