

(Secs. 521, 701, 52 Stat. 1055-1056 as amended, 90 Stat. 574 (21 U.S.C. 360k, 371))

Dated: October 5, 1980.

Jere E. Goyan,

Commissioner of Food and Drugs.

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21 CFR Part 808

[Docket No. 78P-0222]

Medical Devices; Applications for Exemption From Federal Preemption of State and Local Hearing Aid Requirements

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: Massachusetts and Rhode Island have applied to the Food and Drug Administration for exemptions from Federal preemption of their State hearing aid requirements. In this rule the agency is responding to these applications.

EFFECTIVE DATE: November 10, 1980.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Bureau of Medical Devices (HFK-70), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7114.

SUPPLEMENTARY INFORMATION: In the Federal Register of April 13, 1979 (44 FR 22119), FDA published a proposed regulation responding to applications from Massachusetts and Rhode Island for exemption from Federal preemption for certain hearing aid device requirements. Interested persons were given until June 12, 1979 to submit written comments on the proposal. A public hearing on the proposal was held on October 16, 1979, and interested persons were given until November 15, 1979, to submit written comments on matters raised at the hearing.

Elsewhere in this issue of the Federal Register the agency is publishing a final rule responding to applications from 18 other States and the District of Columbia for exemption from preemption for their hearing aid requirements. Some of the issues raised in that proceeding are similar to the issues raised in the comments received on this rule. Because the issues are discussed in greater detail in that regulation, the agency refers interested persons to the preamble to that final rule.

1. One comment objected that the hearing held on the proposed regulation did not comply with the requirements for "informal hearing" specified in section 201(y) of the act (21 U.S.C. 321(y)), especially section 201(y)(1)

which requires that the presiding officer be someone who has not participated in any action which is the subject of the hearing and who is not directly responsible to anyone who has participated in any such action. The comment further objected that the hearing officer did not conduct the hearing in an impartial manner.

Section 201(y) of the act, which sets forth the definition of "informal hearing," does not apply to a hearing conducted under section 521 of the act (21 U.S.C. 360k). An "informal hearing" is required only where that term is specifically used in the act. Section 521 of the act provides for the opportunity for an "oral hearing", rather than an "informal hearing." The agency believes that the record shows that the hearing was conducted fairly and that all parties had an adequate opportunity to present their views.

2. Several comments objected to FDA's proposal to deny exemption from preemption for the Massachusetts provision permitting waiver of the requirement of medical evaluation only if the purchaser's religious beliefs preclude consultation with a physician. Comments also objected to the agency's proposal to deny exemption from preemption for the Rhode Island law, which does not permit a waiver of the requirement of medical evaluation under any circumstances. The FDA regulation (21 CFR 801.420) allows an informed adult 18 years of age or older to waive medical evaluation. Some of the comments argued that medical evaluation is absolutely necessary and, therefore, that no waiver should be permitted. Other comments suggested that only persons with religious objections should be permitted to waive the medical evaluation. Opposing comments agreed with FDA that informed adults should have the freedom to waive medical evaluation. Others suggested that waiver is appropriate in at least certain situations, such as where a purchaser objects to the evaluation for religious reasons or when purchasing replacement hearing aids.

The agency believes that examination by a physician is necessary to ensure that the organic causes of hearing loss are diagnosed and treated properly. The agency, also believes, however, that any informed adult who objects to medical evaluation for religious or personal reasons should be permitted to waive the requirement.

3. Other comments opposing FDA's proposal to deny exemption from preemption for these waiver provisions argued that hearing aid dealers are abusing the FDA waiver provision. Some of these comments suggested that

prospective hearing aid purchasers waive the medical evaluation requirement in 80 to 85 percent of the sales of hearing aids. The Massachusetts Hearing Aid Society surveyed its members and found that 58 percent of the sales of those responding were made to persons who had obtained a prior medical evaluation. The Rhode Island Hearing Aid Society also surveyed its members and found that 62 percent of the sales of those responding were made to persons who had obtained a prior medical evaluation.

FDA has not been presented with any convincing evidence that the waiver provision is being widely abused by hearing aid dealers. The agency conducted a survey of State officials to determine whether they were experiencing any problems with compliance with the FDA hearing aid regulation. Of the 39 States that responded to the survey, only Massachusetts stated that it had encountered major problems with regard to compliance. However, Massachusetts did not document its assertion. Therefore, FDA is denying exemption from preemption for the Massachusetts and Rhode Island waiver provisions.

4. Several comments objected to FDA's proposal to deny exemption from preemption for the Massachusetts provision requiring a hearing test evaluation before the sale of a hearing aid. The Massachusetts law requires that the hearing test be conducted by an otolaryngologist, a physician, or an audiologist. Some comments argued that hearing aid dealers are not qualified to perform the necessary testing and that evaluation by a physician or an audiologist is necessary. Opposing comments argued that hearing aid dealers are qualified to perform the necessary testing. One comment noted that the requirement of medical evaluation is sufficient to ensure that audiometric testing is done as part of the diagnostic process.

There is no evidence that only physicians or audiologists are competent to measure hearing loss. Therefore, the agency does not believe that it is appropriate to require a hearing test evaluation by a physician or an audiologist before every sale of a hearing aid. Problems regarding the competency of hearing aid dealers to measure hearing loss will be adequately addressed by strong State and local licensing provisions.

5. Several comments objecting to FDA's proposal to deny exemption from preemption for the Massachusetts provision requiring that a hearing test evaluation be conducted by an audiologist or a physician argued that

hearing aid dealers are primarily interested in selling hearing aids and, therefore, cannot be expected to perform unbiased testing. Opposing comments disputed the implication that many hearing aid dealers sell hearing aids when the testing shows that an aid is not required. Several comments also noted that some physicians and audiologists now sell hearing aids and, if Massachusetts were permitted to require hearing test evaluation, probably more would sell them.

Although the agency is aware that there are some abuses in the hearing aid industry, it has not been shown that these abuses are so widespread as to justify requiring a hearing test evaluation by a physician or an audiologist before every sale of a hearing aid. The agency believes that the Federal requirements along with stringent State and local licensing laws will adequately address abuses in the hearing aid industry.

6. One comment suggested that FDA should grant Massachusetts an exemption from preemption for its hearing test evaluation requirement as it applies to children under the age of 18. This comment said that granting such an exemption would be consistent with the agency's decisions concerning similar provisions of other State statutes.

FDA agrees with this comment. In the final rule responding to applications from 18 other States and the District of Columbia, published elsewhere in this issue of the *Federal Register*, the agency is exempting from preemption requirements of audiological evaluation for children under the age of 18. Audiologists are specially qualified to assist in the language development and social and educational growth of a child with a hearing loss. Consequently, mandatory audiological evaluation of a minor will serve an important public health purpose. Therefore, the final regulation has been revised to exempt from preemption the Massachusetts hearing test evaluation provision to the extent that it applies to children under the age of 18.

7. FDA is granting an exemption from preemption for Chapter 93, Section 74 of the Massachusetts General Laws, which requires the disclosure of certain information to hearing aid purchasers, on the condition that in enforcing this provision, Massachusetts apply the definition of "used hearing aid" contained in the FDA regulation. There were no comments on this provision.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 521, 701, 52 Stat. 1055-1056 as amended, 90 Stat. 574 (21 U.S.C. 360, 371)) and under authority delegated to the Commissioner

of Food and Drugs (21 CFR 5.1), Part 808 is amended in Subpart C by adding new §§ 808.71 and 808.89 to read as follows:

§ 808.71 Massachusetts.

(a) The following Massachusetts medical device requirements are enforceable notwithstanding section 521 of the act because the Food and Drug Administration has exempted them from preemption under section 521(b) of the act:

(1) Massachusetts General Laws, Chapter 93, Section 72, to the extent that it requires a hearing test evaluation for a child under the age of 18.

(2) Massachusetts General Laws, Chapter 93, Section 74, except as provided in paragraph (6) of the Section, on the condition that, in enforcing this requirement, Massachusetts apply the definition of "used hearing aid" in § 801.420(a)(6) of this chapter.

(b) The following Massachusetts medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them exemptions from preemption under section 521(b) of the act.

(1) Massachusetts General Laws, Chapter 93, Section 72, except as provided in paragraph (a) of this section.

(2) Massachusetts General Laws, Chapter 93, Section 74, to the extent that it requires that the sales receipt contain a statement that State law requires a medical examination and a hearing test evaluation before the sale of a hearing aid.

§ 808.89 Rhode Island.

The following Rhode Island medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them an exemption from preemption under section 521(b) of the act: Rhode Island General Laws, Section 5-49-2.1, and Section 2.2, to the extent that Section 2.2 requires hearing aid dispensers to keep copies of the certificates of need.

Effective date. This regulation is effective November 10, 1980.

(Secs. 521, 701, 52 Stat. 1055-1056 as amended, 90 Stat. 574 (21 U.S.C. 360, 371))

Dated: October 5, 1980.

Jere E. Goyan,

Commissioner of Food and Drugs.

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21 CFR Part 808

[Docket No. 77N-0333]

Exemption From Preemption of State and Local Hearing Aid Requirements; Applications for Exemption

AGENCY: Food and Drug Administration.
ACTION: Final rule.

SUMMARY: Various States have applied to the Food and Drug Administration for exemptions from Federal preemption of their State hearing aid requirements. In this rule the agency grants exemptions for some State hearing aid requirements and denies exemptions for others.

EFFECTIVE DATE: November 10, 1980.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Bureau of Medical Devices (HFK-70), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7114.

SUPPLEMENTARY INFORMATION: The proposal upon which this final regulation is based was published in the *Federal Register* of July 28, 1978 (43 FR 33180). Interested persons were initially given until September 26, 1978 to comment on the proposal. In the *Federal Register* of October 20, 1978 (43 FR 49015), the comment period was extended to December 19, 1978. In the *Federal Register* of October 20, 1978 (43 FR 49014), the agency also published a proposed regulation addressing a New Jersey requirement that it had not addressed in the July 28 proposal. Interested persons were given until December 19, 1978 to comment on this proposal. FDA held a public hearing on these proposed regulations on October 31 and November 1, 1978.

A proposed regulation responding to applications from Massachusetts and Rhode Island for exemption from preemption for their State hearing aid requirements was published in the *Federal Register* of April 13, 1979 (44 FR 22119). Interested persons were given until June 12, 1979 to comment on the proposed regulation. This final rule does not include the agency's response to the applications from these two States which is set forth in a final rule published elsewhere in this issue of the *Federal Register*.

Although FDA is denying exemption from preemption for many State requirements, it encourages the States to remain active in regulating the hearing aid industry. FDA particularly encourages the States to adopt strict licensing laws to establish and maintain minimum competency requirements for persons who test for hearing loss and select and fit hearing aids. FDA also encourages State and local governments

to educate consumers about the value of medical evaluation prior to the purchase of a hearing aid and to furnish them with the information they need for proper hearing health care. States may assist in enforcing the FDA hearing aid regulations by adopting requirements identical to the FDA requirements.

In addition to the testimony at the public hearing, the agency received more than 300 comments on the proposed regulation. Most of these comments addressed the issue of mandatory audiological evaluation. Many comments also addressed waiver of medical evaluation, disclosure requirements, and the California provision restricting the advertising of hearing aids. The following is a summary of the comments and the agency's response to them.

The FTC Rule

1. The Federal Trade Commission (FTC) also has been studying the hearing aid health care delivery system to determine what steps should be taken to protect consumers from unfair or deceptive acts or practices in the sale of hearing aids. In the Federal Register of June 24, 1975 (40 FR 26646), the FTC published an "initial notice" of a proposed trade regulation rule for the hearing aid industry. Public hearings on the proposed rule were held in various cities from April to August of 1976. The presiding officer at these hearings reported his findings and conclusions on August 1, 1977. The staff then analyzed the record and made its report and recommendation to the FTC on September 25, 1978. Interested persons were given 60 days to comment on the staff report. The rule is now awaiting final action by the FTC.

The most important provision of the proposed rule is a requirement that the purchaser of a hearing aid be given the right to cancel the purchase for any reason at any time within 30 days of delivery, and receive a refund of most of the purchase price (in effect, a mandatory trial rental period). Other important features of the rule are that it would prohibit certain misleading claims and sales practices with respect to hearing aids and would require the hearing aid dealer to obtain prior express written consent to a sales visit in the buyer's home or office.

One comment on the FDA proposal said the FTC record is replete with evidence that hearing aid dealers receive little training and so are often incompetent to test hearing and to select and fit hearing aids. The comment also said the FTC record shows that hearing aid dealers do not counsel hearing-impaired persons adequately in

adapting to a hearing aid and that they do not repair hearing aids well. Finally, the comment said the FTC record shows that hearing aid dealers abuse home visits. The comment recommended that independent audiological evaluation should be required to remedy these abuses.

The FTC record does indeed contain evidence of many abuses in the hearing aid industry. It should be noted, however, that most of the evidence in the FTC record was gathered before the FDA regulation became effective on August 25, 1977. FDA believes that its regulation has already reduced some abuses in the industry and that adoption of the FTC rule would reduce these abuses even further. FDA also believes that stringent State and local licensing laws will ensure that hearing aid dealers are competent to test hearing and to select and fit hearing aids. The agency believes that the Federal requirements, along with strong State and local licensing laws, will adequately address the abuses in the hearing aid industry described in the FTC staff report.

The Legality and Constitutionality of the Proposed Rule

2. One person combined comments on the proposal with a petition to amend the FDA hearing aid regulation.

FDA will respond to the petition separately in a letter to the petitioner and will place a copy of the response on file with the Hearing Clerk, Food and Drug Administration.

3. One comment argued that the regulation is illegal and unconstitutional in several respects. First, the comment argued that the FDA regulation does not preempt State requirements for audiological evaluation because the constitutional requirements for preemption set forth in *Hines v. Davidowitz* (312 U.S. 52 (1941)) are not satisfied—specifically, that a State requirement is preempted only if it obstructs the "accomplishment and execution of the full purposes and objectives of an act of Congress." The comment reasoned that the requirement of audiological evaluation before the sale of a hearing aid does not relate to the safety or effectiveness of hearing aids and, consequently, does not interfere with the Federal regulation.

In section 521 of the act (21 U.S.C. 360k) Congress expressed its purposes and objectives with respect to the preemption of State and local medical device requirements. That section reflects Congress' intent that the Food, Drug, and Cosmetic Act preempt any State or local requirement applicable to a medical device that is different from or in addition to a requirement for the

device under the act. The State requirement of audiological evaluation relates to the safety or effectiveness of hearing aids because it is intended to ensure that the purchaser is fitted properly with a hearing aid that will benefit his or her hearing ability. This requirement is in addition to the Federal requirements applicable to hearing aids and would interfere with the execution and accomplishment of the objectives of FDA's hearing aid regulation. Therefore, the State requirement of audiological evaluation is preempted in accordance with both *Hines v. Davidowitz* and section 521 of the act.

4. The comment further argued that the Tenth amendment, which reserves to the States those powers not specifically granted to the Federal government, limits the power of Congress to regulate interstate commerce in areas traditionally regulated by the States, such as occupational licensing and consumer protection. The comment stated that audiological evaluation does not involve interstate commerce. The comment also objected that FDA is requiring the States to enforce the Federal regulatory scheme by changing their State laws to prohibit audiological evaluations, contrary to the holdings in *Brown v. Environmental Protection Agency*, 521 F.2d. 827 (9th Cir. 1975) and *District of Columbia v. Train*, 521 F.2d. 97 (D.C. Cir. 1975).

Congress enacted the Medical Device Amendments of 1976 (Pub. L. 94-295) pursuant to its authority to regulate interstate commerce under Article 1, Section 8 of the United States Constitution. The purpose of the amendments is to ensure that medical devices are safe and effective. When Congress determines that it is necessary to regulate a particular area of interstate commerce, it may also regulate any incidental aspects of that area that it believes may affect interstate commerce. *Heart of Atlanta Motel v. United States*, 379 U.S. 241 (1964); *Katzenbach v. McClung*, 379 U.S. 294 (1976); *United States v. Darcy*, 312 U.S. 100 (1941). In enacting section 520(e) of the act, Congress determined that the safety and effectiveness of certain medical devices may be ensured only by restricting their sale, distribution, or use. Section 520(e) of the act, therefore, is a valid exercise of congressional authority under the commerce clause. In restricting the sale of hearing aids, FDA acted in accordance with the authority granted it under section 520(e). Therefore, Neither FDA's restrictions on the labeling and conditions for sale of hearing aids nor its decision to deny exemptions from preemption for State

requirements of amendatory audiological evaluation is in violation of the Tenth amendment.

FDA's action is not contrary to the holdings in *Brown v. EPA* and *District of Columbia v. Train*. FDA is not requiring the States to enforce a Federal regulatory scheme, nor is it requiring them to prohibit audiological evaluation. The effect of FDA's denying an exemption from preemption for the requirement of audiological evaluation is to make such evaluations optional for the patient. By denying exemption for this requirement, the agency is recognizing Congress' intent that FDA regulations applicable to devices, such as hearing aids, preempt State and local requirements that are different from or in addition to the FDA requirements.

5. The comment also noted that under section 520(e) of the act, FDA may restrict the use of a device to persons with specific training, skill, education, or experience only if it determines that such a restriction is necessary to ensure the safe and effective use of the device. The comment argued that FDA has made no such finding with respect to the use of hearing aids by audiologists.

FDA is not excluding audiologists from the use of hearing aids. Because the FDA hearing aid regulation preempts State laws requiring audiological evaluation, the States may not require, as a condition to the purchase of a hearing aid, that the prospective purchaser receive an audiological evaluation. However, audiologists may continue to conduct hearing tests.

6. The comment also argued that, even if Congress did intend to preempt State laws requiring audiological evaluation, the procedures in Part 808 (21 CFR Part 808), pursuant to which FDA has considered the applications that are the subject of this rule, are unconstitutional and unlawful because the criteria for determining whether to grant an exemption are not in accord with the constitutional standard for preemption. The comment stated that the correct standard for the agency to apply is first to determine whether there is a congressional intent to occupy the field, and then to determine whether the State policy obstructs the full purpose and objectives of the act or whether Federal and State policies seek the same objectives and can coexist. The comment also stated that in denying an exemption FDA must show that a conflict between Federal and State regulation would necessarily result if the exemption were granted. Finally, the comment stated that FDA has no authority to consider factors such as cost and availability of services in

determining whether to grant an exemption from preemption.

The comment misconceives the law regarding Federal preemption. There are two types of Federal preemption: Express and implied. The standard described in the comment is the test of implied Federal preemption, the test applicable where Congress has not exercised its power under the Commerce clause to expressly declare Federal law paramount to State law. See *Jones v. Rath Packing Co.*, 430 U.S. 519 (1977); *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132 (1963); *Hines v. Davidowitz*, 312 U.S. 52, 56 (1940). In section 521(a) of the act, however, Congress has expressly declared that the Federal Food, Drug, and Cosmetic Act preempts any State or local requirement with respect to the safety or effectiveness of a medical device that is different from or in addition to a requirement under the act applicable to the device. The test of implied Federal preemption, therefore, does not apply. Adoption of the standard advanced in the comment would render section 521 of the act meaningless because as argued in the comment the Federal law would preempt only State requirements that directly conflict with the Federal law. Yet, in section 521 of the act Congress established a specific standard of preemption. Under Section 521(a) of the act, preemption is not restricted to State requirements that directly conflict with Federal law, but rather extends to requirements that are different from, or in addition to, any requirement applicable to the device under the act.

The comment's contention that, in denying an exemption, FDA must show that a conflict between Federal and State regulation would necessarily result if an exemption were granted confuses the test of preemption with the standard FDA must apply in deciding whether to exempt State and local requirements from preemption. As stated above, section 521(a) of the act specifies the type of State or local requirement that is preempted. In section 521(b) of the act, Congress authorized FDA to exempt a State or local requirement from Federal preemption if it is more stringent than the Federal requirement or if it is required by compelling local conditions and compliance with the requirement would not cause the device to be in violation of the act. Thus, FDA is not required to show that a conflict between Federal and State law would necessarily result if a State requirement were exempted from preemption.

The authority granted FDA in section 521(b) of the act to exempt State or local

requirements from preemption is discretionary. Congress did not specify the criteria that FDA must employ in exercising that discretion. In light of the purpose of the act and the Medical Device Amendments, however, FDA believes that in deciding whether to exempt a State requirement from preemption it is appropriate to consider the effect that granting the exemption would have on the public health. The cost of medical devices and the availability of medical services are relevant factors in assessing the effect that an exemption would have on the public health. Therefore, FDA will consider these factors in determining whether to exempt a particular State requirement from preemption.

7. The comment also stated that proposed § 808.1(d)(5) (21 CFR 808.1(d)(5)), which provides that section 521(a) of the act does not preempt criteria for payment of State or local obligations under Medicaid and similar health care programs, is unlawful because section 521(a) of the act preempts all State or local requirements relating to medical devices.

Under section 521(a) of the act, the Food, Drug, and Cosmetic Act preempts only State or local requirements that relate to the safety or effectiveness of medical devices. In order for a State provision to be a requirement with respect to a device within the meaning of section 521 of the act—and thereby a candidate for preemption—it must relate to the device itself. Rules or requirements established by Federal, State, or local agencies to control the expenditure of public funds for purchasing hearing aids and hearing health care services for the hearing impaired, i.e., third-party payment programs, typically establish standards for the screening and diagnosis of individuals who will receive hearing aids through publicly funded programs. These requirements are designed to ensure the proper use of public funds. Rules and requirements for the expenditure of public funds for hearing aids are payment criteria established by the payer or purchaser and are not "requirements with respect to a device" within the meaning of section 521(a) of the act. Consequently, these requirements are not preempted under section 521(a). It should be noted, however, that regardless of the criteria for payment, the hearing aid dispenser is required to comply with the FDA regulation.

8. The same comment also argued that the proposal to exempt from preemption State laws requiring that a hearing aid purchaser be examined by an

otolaryngologist violated section 520(e) of the act. Section 520(e)(1) of the act provides that no restriction placed on a device under section 520(e)(1)(B) may exclude a person from using a device solely because the person does not have the training or experience to be eligible for certification by a certifying board recognized by the American Board of Medical Specialties or has not been certified by such a board.

Section 520(e) of the act limits the restrictions that FDA may place on the sale, distribution, or use of a device. That section does not limit FDA's authority to exempt State or local requirements from preemption, nor does it provide that FDA may exempt from preemption only requirements that it has the authority to impose. In any event, although FDA believes that it has the authority to exempt from preemption the requirement of examination by an otolaryngologist, it is denying exemption for this requirement because it may be a barrier to the receipt of a hearing aid in areas where otolaryngologists are not readily available.

9. Finally, the same comment objected that the hearing held on the proposed regulation did not comply with the requirements of an "informal hearing" specified in section 201(y) of the act (21 U.S.C. 321(y)), especially section 201(y)(5), which requires that the presiding officer prepare a written report of the hearing to which he or she shall attach all written material presented at the hearing.

An "informal hearing," as defined in section 201(y) of the act, is required only where the term "informal hearing" is specifically used in the act. For example, an "informal hearing" is required under sections 304(g), 515, and 516. An informal hearing is often referred to as a regulatory hearing and is governed by Part 16 of the agency's administrative regulations (21 CFR Part 16). Section 521 of the act provides for the opportunity for an oral hearing, rather than an "informal hearing," on a proposed regulation on an application for exemption from preemption. The public hearing required by section 521 of the act is sometimes referred to as a legislative hearing and is governed by Part 15 (21 CFR Part 15) of the agency's administrative regulations. Indeed, 21 CFR 15.1(b) expressly states that Part 15 governs any hearing relating to exemptions from preemption of requirements for device.

Audiological Evaluation

Almost all the comments on the proposed regulation addressed FDA's proposal to deny exemption from preemption for State laws requiring

audiological evaluation before the sale of a hearing aid to an adult. The comments focused on the value, cost, and availability of audiological evaluation.

10. Many comments in favor of exempting from preemption State laws requiring mandatory audiological evaluation objected to FDA's conclusion that audiological evaluation would not provide conclusive assurance that the patient would benefit from amplification. Some argued that FDA should not require that such conclusive assurance be shown. Many comments stated that there is widespread misvaluation of hearing loss by hearing aid dealers. The comments also argued that audiologists are better qualified than are hearing aid dealers to test hearing and that, because audiologists do not sell hearing aids, their evaluations are unbiased and, hence, more reliable.

Comments supporting FDA's proposal to deny exemption to these requirements stated that mandatory audiological evaluation would be superfluous because only physicians can perform the necessary medical tests and hearing aid dealers can perform the audiometric tests. These comments also disputed the contention that there is widespread misvaluation of hearing loss by hearing aid dealers. Several comments pointed out that not all audiologists are unbiased testers because some audiologists sell hearing aids and, if audiological evaluation were mandatory, probably more audiologists would begin selling them.

After reviewing the conflicting information in the public record regarding the predictive value of audiological testing in determining whether a patient would benefit from a hearing aid, FDA has concluded that audiological evaluation is not necessary to provide reasonable assurance of the safety or effectiveness of hearing aids. There is no evidence that audiological evaluation reduces or eliminates any risk to health presented by a hearing aid. The primary risk to health presented by hearing aids is the possibility that an unnecessary or only partially effective hearing aid will be substituted for necessary medical or surgical treatment, thus depriving the hearing-impaired patient of the benefit of appropriate diagnosis and care and resulting in a detriment to health. Medical evaluation by a licensed physician will ensure that all medically treatable conditions are accurately identified and properly treated before a hearing aid is bought. Potential problems involving misvaluation of

hearing loss or misfitting of hearing aids will be adequately addressed by strong State and local licensing laws for hearing aid dispensers and by the trial rental period required by the draft final FTC regulation. Moreover, there is no evidence that only audiologists are competent to measure hearing loss and to fit hearing aids. Finally, FDA did not require that conclusive evidence be shown that the patient would benefit from amplification. Rather, the agency concluded that the requirement of mandatory audiological evaluation would increase the cost of obtaining a hearing aid without providing any conclusive assurance that the patient would benefit from amplification.

11. Many comments challenged FDA's conclusion that mandatory audiological evaluation would increase the cost of a hearing aid. These comments reasoned that if an audiological evaluation were done, the hearing aid dealer would not have to perform further testing. Other comments noted the low cost of hearing aids in certain public dispensing programs that require audiological evaluation, such as the Veteran's Administration. Many comments argued that mandatory audiological evaluation would result in a net savings to the consumer because the better testing provided by audiologists would result in fewer misvaluations and, therefore, fewer sales of hearing aids to persons who could not benefit from them.

Many comments supported FDA's proposal to deny exemption from preemption for State laws requiring mandatory audiological evaluation. Many hearing aid dealers stated that they do not reduce the cost of a hearing aid by the cost of an audiological evaluation if such an evaluation has already been made because they cannot rely on testing done by an audiologist with whom they are not familiar. Consequently, hearing aid dealers frequently perform hearing tests even after an audiological evaluation has been made. Many comments also disagreed with the contention that mandatory audiological evaluation would result in fewer misvaluations of hearing loss and therefore a net savings to the consumer.

The evidence whether mandatory audiological evaluation would increase the cost of a hearing aid is conflicting and inconclusive. Some hearing aid dealers said they would reduce the cost of a hearing aid if the prospective purchaser had an audiological evaluation; others said they would not. Many of the comments that purported to show that audiological evaluation would reduce the cost of a hearing aid actually

described governmental or clinical programs where any savings were attributable to the fact that the program was nonprofit and not to the fact that an audiological evaluation had been made. Thus, it appears that mandatory audiological evaluation would result in an increase in cost in some cases and a decrease (or at least no increase) in cost in other cases. It is not clear what the predominant effect of such a requirement would be. FDA believes that the amount of unnecessary costs that may be incurred as a result of misvaluation of misfitting would be reduced more efficiently by stricter State licensing laws and a trial rental period as required in the draft final FTC regulation than by mandatory audiological evaluation.

12. Many comments agreed with FDA's conclusion that audiologists are not readily available in certain areas of the country. Many comments noted that while audiologists may be available in urban areas they are scarce in rural areas. Some comments pointed out that few audiologists are engaged in private practice and, therefore, few are available to conduct hearing tests for the general public.

Many comments disputed FDA's conclusion that audiologists are scarce in certain areas of the country. Comments from various States said that audiologists are widely available in their jurisdictions. Many of these comments cited statistics or supported their claims in other ways.

There is conflicting evidence with respect to the availability of audiologists. Although audiologists may be readily available in and around large cities, it appears from the comments that they are scarce in most rural areas. Many elderly people could not easily travel 25 or 50 miles to visit an audiologist. Mandatory audiological evaluation, therefore, would sometimes prohibit a patient who could be helped by a hearing aid from obtaining one.

After considering all the factors discussed above, FDA has decided to deny exemption from preemption for State and local laws requiring audiological evaluation before the sale of a hearing aid to an adult. It has not been shown that audiological evaluation is necessary to provide reasonable assurance of the safety or effectiveness of hearing aids. Furthermore, mandatory audiological evaluation may increase the cost of a hearing aid and create an additional barrier to the receipt of a hearing aid in those areas of the country where audiological services are scarce.

The agency would like to set aside a few apparent misconceptions. Neither the FDA regulation on hearing aids nor

the agency's decision in this regulation to deny exemption from preemption for state laws requiring mandatory audiological evaluation. Audiologists may continue to test hearing before the sale of a hearing aid. FDA does not question the competency of audiologists. Indeed, FDA recognizes that the audiologist is an important member of the hearing health care team qualified to provide basic audiometric evaluation, hearing aid orientation, auditory training, speech reading, speech conservation, language development, and counseling and guidance services. FDA expects physicians to refer patients to an audiologist when necessary. Likewise, FDA's decision to deny exemption from preemption for these requirements does not constitute a determination that a hearing test is unnecessary before the sale of hearing aid. FDA has determined only that it is not necessary to require that this testing be done by an audiologist to provide reasonable assurance of the safety and effectiveness of hearing aids.

13. Comments from physicians, audiologists, and hearing aid dealers supported FDA's proposal to exempt from preemption State requirements of audiological evaluation for children.

FDA agrees with these comments and, therefore, is granting exemption from preemption to State laws requiring audiological evaluation before the sale of a hearing aid to a minor. Audiologists are specially qualified to assist in the language development and educational and social growth of a child with hearing loss. Consequently, mandatory audiological evaluation of a minor will serve an important public health purpose.

Waiver

14. Many comments addressed the issue of waiver of medical evaluation. The FDA regulation permits any informed adult 18 years or older to waive the medical evaluation requirement. Some State laws do not permit a waiver of the medical evaluation requirement under any circumstances. Others permit a waiver only if the prospective purchaser objects to medical evaluation for religious reasons. FDA proposed to deny exemptions from preemption for those State and local requirements that either do not permit a waiver of a medical evaluation requirement or permit a waiver for religious reasons only.

Some comments favoring exemption from preemption for State laws limiting or prohibiting waiver of medical evaluation argued that medical evaluation is absolutely necessary and, therefore, that a waiver should not be

permitted. Other comments suggested that only persons with religious objections should be permitted to waive the medical examination. Several comments stated that it is easy for hearing aid dealers, eager to make a sale, to induce the purchaser to waive medical evaluation without violating the FDA regulation by actively encouraging the waiver. Other comments said that hearing aid dealers are widely abusing the waiver provision. For instance, the Attorney General of Massachusetts asserted that prospective hearing aid purchasers waive the medical evaluation requirement in 85 percent of the sales of hearing aids in Massachusetts.

The comments supporting FDA's proposal to deny exemption from preemption for State requirements limiting or prohibiting waiver of medical evaluation generally agreed with FDA that informed adults should have the freedom to waive medical evaluation. One religious group argued that failure to allow waiver of medical evaluation would violate the rights of its members. Many comments disputed the contention that the waiver provision is being widely abused. One comment pointed out that most of the waivers identified in a recent New York study were exercised by persons who already owned a hearing aid, and that only 6 percent of the persons purchasing a hearing aid for the first time waive medical evaluation. This was confirmed by a limited survey in Massachusetts, which showed that only 8 percent of first-time users of a hearing aid waived the requirement for medical evaluation.

FDA believes that, before purchasing a hearing aid, all prospective hearing aid users should obtain a medical evaluation of hearing loss to determine whether any conditions exist that could be corrected by medical treatment or surgery. FDA recognizes, however, that the risk to health posed by hearing aids arises from the failure to obtain beneficial medical treatment rather than from wearing a hearing aid. FDA believes that any informed adult who objects to medical evaluation for religious or personal reasons should be permitted to waive the medical evaluation requirement.

FDA has not been presented with any convincing evidence that the waiver provision is being widely abused by hearing aid dealers. The Attorney General of Massachusetts provided no evidence to support its claim that the waiver privilege is being exercised in 85 percent of the sales of hearing aids in that Commonwealth. FDA undertook a survey of Attorneys General and

hearing aid dealer licensing boards to determine whether they were experiencing any problems with compliance with the FDA regulation. Of the 39 States that responded to this survey, only 19 provided FDA with information pertaining to dealer compliance with the regulation. Twenty-five of these 31 States indicated that they had not received complaints or other information regarding dealer compliance with the regulation, although a few of these 25 States related unsubstantiated rumors of noncompliance. Six of the 31 States responding to the survey indicated that they had encountered problems involving compliance with FDA regulation but, of these six, only Massachusetts stated that compliance problems were more common than isolated incidents. Therefore, FDA is denying exemption from preemption for State laws limiting or prohibiting waiver of medical evaluation. Exempting these requirements will also permit the purchase of a hearing aid in the rare circumstance where an individual would have great difficulty obtaining a medical evaluation because of the lack of a physician in the area.

15. In the proposed regulation, FDA proposed to grant exemptions from preemption for requirements that prohibit a waiver when certain medical conditions are found to exist in the prospective purchaser. Comments have persuaded FDA to deny exemption from preemption for these State requirements. FDA believes that an informed adult should be permitted to waive a medical evaluation even if one of these conditions is present. The existence of such a condition does not necessarily mean that the individual could not safely benefit from using a hearing aid. Moreover, the FDA hearing aid regulation requires that the User Instructional Brochure contain a statement warning hearing aid dispensers to advise a prospective purchaser to consult promptly with a licensed physician (preferable a physician who specializes in diseases of the ear) if the dispenser learns of the existence of any of eight specified medical conditions. FDA expects that hearing aid dispensers will be conscientious in impressing the importance of a medical examination upon prospective users exhibiting any of these symptoms.

16. Many States, while not requiring that the purchaser be examined by a physician, require hearing aid dispensers to advise in writing a prospective purchaser who has one or more of certain listed medical

conditions to consult with a physician. Some States also require that the hearing aid dispenser furnish the prospective purchaser with the names and addresses of physicians or otolaryngologists in the area. FDA has proposed to deny exemption from preemption for these requirements.

These requirements are more stringent than the FDA regulation because they require the dispenser to advise the prospective purchaser in writing. This requirement places only a slight additional burden on the dispenser and does not conflict with the FDA requirement. Therefore, the agency is exempting these requirements from preemption. FDA's requirements with respect to medical evaluation and waiver still apply in these States.

Disclosure Requirements

17. Many State regulations require that the hearing aid dispenser provide the purchaser with certain information at the time of sale. Most States require that this information be included in a sales receipt, while some States require that the information be included on the package. Much of the required information relates to the terms of sale and not to the safety or effectiveness of hearing aids. To this extent, these provisions are not preempted and, consequently, are not candidates for exemption. Many of these provisions, however, do relate to the safety or effectiveness of hearing aids and, therefore, are preempted. These preempted provisions generally require that the receipt state whether the hearing aid is new, used, or reconditioned. Many States also require that the receipt or packaging include a statement that a hearing aid will not prevent or improve organic causes of hearing loss.

Several comments objected to FDA's proposal to grant exemptions to the preempted State requirements described above. The comments argued that the User Instructional Brochure required by the FDA regulation contains all of the information the consumer needs and, consequently, that it is unnecessary to require that the information be included on the sales receipt and on the packaging as well. Manufacturers of hearing aids also objected that permitting certain States to require that specific statements be placed on the packaging of a hearing aid would create an unreasonable burden because they do not always know the ultimate destination of every hearing aid package.

These requirements are more stringent than the Federal requirements. FDA believes that the additional information

required by these State provisions may be useful to the consumer and will not impose a significant burden on the hearing aid dispenser or manufacturer. Although some of the information required to be included on the receipt is also contained in the User Instructional Brochure, FDA believes that inclusion of the information in both places will increase the likelihood that it is brought to the attention of the consumer. Moreover, the additional information required to be included on the packaging can be added at the time of sale. Therefore, FDA is granting exemption from preemption for these requirements. To ensure uniformity, the agency is requiring that the States apply the Federal definition of "used hearing aid" (21 CFR 801.420(a)(6)) in enforcing their disclosure requirements.

Arizona

18. As proposed, FDA is denying exemption from preemption for Arizona Revised Statutes (A.R.S.), Chapter 17, Section 36-1901.7(s) and its implementing regulation, Arizona Code of Revised Regulations (A.C.R.R.), Title 9, Article 3, R-9-16-303. These provisions are less stringent than the FDA regulation because they allow the dispensing of a hearing aid to a child 14 years of age or under by permitting the parent or guardian of the child to waive the medical evaluation requirement.

Several comments opposed FDA's proposal to grant exemption from preemption for A.R.S. Chapter 17, Section 36-1901.7(t) and its implementing regulation, A.C.R.R. Title 9, Article 3, R-9-16-304. These provisions require that a prospective hearing aid user with a significant air bone gap or apparent unilateral sensorineural hearing loss receive an audiological evaluation, although they permit a waiver of this requirement. The comments argued that this State requirement places audiological evaluation on a par with medical evaluation and that this is inconsistent with the position of FDA that audiological evaluation is not necessary to provide reasonable assurance of the safety or effectiveness of hearing aids. One comment argued that this requirement may mislead people into believing that audiological evaluation is as important as medical evaluation.

FDA agrees with these comments and, therefore, is denying exemption from preemption for these provisions.

California

19. Section 26463(m) of the California Health and Safety Code provides that it is unlawful to advertise any drug or device represented to have an effect on

diseases or disorders of the ear, including hearing loss and deafness. A group of persons with impaired hearing brought an action under this section to enjoin certain advertising by Dahlberg Electronics, Inc., a dispenser of hearing aids. The California Superior Court granted the injunction, and its decision was upheld by the Court of Appeals of California (144 Cal. Rptr. 585 (1978)). The California Supreme Court denied a hearing on the case, and the United States Supreme Court denied an appeal (—U.S.—, 1979).

The Court of Appeals held that section 26463(m) prohibits persons from advertising that hearing aids have any effect on hearing loss or deafness, including representations that the aids have a compensatory effect. The court held that the injunction does not prohibit Dahlberg from advertising its places of business, the fact that Dahlberg hearing aids are sold there, the prices of the instruments, or other information of a similar nature. The Court of Appeals also held that section 26463(m) is not preempted by section 521 of the Federal Food, Drug, and Cosmetic Act because (1) section 26463(m) is a prohibition and therefore not a requirement within the meaning of section 521; and (2) FDA has not declared hearing aids to be restricted devices under section 520(e) of the act and, therefore, that FDA does not regulate the advertising of hearing aids.

The agency proposed to exempt section 26463(m) from preemption because it is more stringent than the Federal requirements. The agency specifically requested comments on whether section 26463(m) relates to the safety or effectiveness of hearing aids.

Some comments argued that section 26463(m) is not preempted because it is not inconsistent with any FDA requirement. Other comments argued that, if section 26463(m) is preempted, it should be exempted from preemption. These comments reasoned that, because advertising may be used to induce people to buy a hearing aid without a medical evaluation, the California requirement is more stringent than the FDA regulation in that it permits the State to exercise greater control in enforcing the requirement of medical evaluation.

Some comments argued that section 26463(m) is preempted and that it should not be exempted from preemption. These comments interpreted the section to prohibit truthful advertising and to require hearing aid manufacturers to prepare different advertising for California than for the rest of the country. Several comments suggested that section 26463(m) would even

prohibit the User Instructional Brochure from containing some statements required by the Federal regulation. However, the California Department of Health argued that the User Instructional Brochure is not subject to section 26463(m) because it is not advertising.

FDA believes that section 26463(m) is preempted by section 521 of the act. Section 521 preempts any State or local requirement that is different from or in addition to any requirement applicable to the device under the act which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act. FDA has declared hearing aids to be restricted devices under section 520(e) of the act (42 FR 9291; February 15, 1977). Section 502(q) of the act (21 U.S.C. 352(q)) provides that a device declared to be restricted under section 520(e) of the act is misbranded if its advertising is false or misleading in any particular. Section 26463(m) is different from section 502(q) as applied to hearing aids because it prohibits not only false and misleading advertising but also truthful representations that hearing aids have an effect on hearing loss. FDA does not accept the argument that section 26463(m) is not preempted because it is a "prohibition" and therefore not a "requirement" within the meaning of section 521 of the act. Clearly, Congress intended to include prohibitions within the meaning of "requirements" in section 521 of the act. Indeed, many of the "requirements" in the act are prohibitions. Prohibitions can conflict with Federal policy as easily as any other type of requirement.

The comments have persuaded FDA to deny exemption from preemption for section 26463(m) because it would prohibit not only false and misleading advertising but also truthful advertising. Although the California law provides a procedure by which manufacturers may receive prior approval of advertising that would otherwise be prohibited by section 26463(m), FDA does not believe that manufacturers should be required to follow this procedure. Section 26463(m) creates a burden on interstate commerce because the nationwide manufacturer is forced to either tailor all its advertising to comply with the California requirements or not advertise in California at all. Therefore, FDA is denying exemption from preemption for section 26463(m) to the extent that it applies to hearing aids.

20. California also sought exemption from preemption for sections 3365 and 3365.6 of its Business and Professions Code.

The agency is granting exemption from preemption for section 3365, which requires hearing aid dispensers to provide the purchaser with a receipt containing certain information. Comments on this type of provision are discussed in paragraph 17 above, under the heading "Disclosure Requirements."

FDA is also granting exemption from preemption for § 3365.6, which provides that no hearing aid may be sold to a person 16 years of age or younger unless the person has been examined by an otolaryngologist and an audiologist. Comments on this type of provision are discussed in paragraph 13 above.

21. The agency advises that a proposal responding to another California application for exemption published in the *Federal Register* of February 15, 1977 (42 FR 9186) was editorially revised for clarity in a reproposal published in the *Federal Register* of April 3, 1979 (44 FR 19438). One effect of this reproposal was to eliminate proposed paragraphs (a)(1) through (a)(12) in § 808.55. The organization of § 808.55 in this final regulation has been revised to reflect this change. To further the agency's goals of writing clear and understandable regulations, all sections of Part 808 included in this final rule have been editorially revised in a manner similar to that in the April 3, 1979 reproposal.

Connecticut

22. FDA is granting exemption from preemption for Connecticut General Statutes section 20-403, which requires hearing aid dispensers to advise prospective purchasers in writing to consult with a physician if any of eight specified medical conditions are found to exist. This type of provision is discussed in paragraph 16 above.

FDA is also exempting from preemption section 20-404, which requires that a person under the age of 18 be examined by an otolaryngologist and an audiologist before the sale of a hearing aid. This type of provision is discussed in paragraph 13 above.

Florida

23. FDA proposed to exempt from preemption Florida Statutes section 468.135(5) and Florida Administrative Code section 10D-48.25(26). These sections prohibit a waiver of medical evaluation when certain medical conditions are observed in the prospective purchaser. As discussed in paragraph 15 above, comments have persuaded FDA to deny exemption from preemption for such provisions. Thus, in this final rule, § 809.59 denies exemption from preemption for Florida Statutes

section 468.135(5) and Florida Administrative Code section 10D-48.25(26).

Kentucky

24. Section 334.200(1) of Kentucky Revised Statutes prohibits the sale of a hearing aid unless, within the preceding 90 days, the purchaser has been examined by a licensed physician and has received an audiological evaluation. The section permits adults to waive these requirements. Several comments supported FDA's proposal to exempt section 334.200(1) from preemption, agreeing that it is more stringent than the FDA regulation and that, because it permits a waiver, it does not create problems with respect to the cost or availability of audiological evaluation.

Comments opposing FDA's proposal argued that this section should not be exempted from preemption because, although it permits a waiver by requiring audiological evaluation it may mislead people into believing that evaluation by an audiologist is necessary.

FDA agrees with the comments opposing the exemption from preemption of this section. Audiological evaluation should not be required, even if a waiver is permitted, because it has not been shown that evaluation by an audiologist is necessary to ensure the safety or effectiveness of hearing aids. Also, the Kentucky requirement may erect an unnecessary barrier to the purchase of a hearing aid by leading people to believe that audiological evaluation is as important as medical evaluation. Therefore, in final § 808.67, the agency denies exemption from preemption for section 334.200(1).

Maine

25. FDA is granting exemption from preemption for Maine Revised Statutes Annotated (M.R.S.A.) section 1658-C, which requires a hearing aid dispenser to give a notice containing certain information to the purchaser at the time of sale. This type of provision is discussed in paragraph 17 of this preamble. As a condition to exemption, the agency is requiring that Maine apply the FDA definition of "used hearing aid" to ensure uniformity.

26. FDA is denying exemption from preemption for M.R.S.A. section 1658-D, which requires that any person 18 years of age or younger and any adult with certain medical conditions must be examined by an otolaryngologist or an audiologist before purchasing a hearing aid. This section is less stringent than the FDA regulation because it permits the sale of a hearing aid on the recommendation of an audiologist without a medical evaluation by a

licensed physician. The State of Maine submitted a comment agreeing that section 1658-D is less stringent than the FDA regulation and, therefore, may not be exempted from preemption. FDA is also denying exemption from preemption for the last sentence of section 1658-E, which states that the requirements of section 1658-D do not apply to a person who objects to them for religious reasons. The other portions of section 1658-E are not preempted.

Minnesota

27. Minnesota Statutes section 145.43 provides that no hearing aid may be sold except upon the written recommendation of an audiologist, otolaryngologist, otologist, or licensed medical doctor. Section 145.44 provides that an adult under 60 years of age may waive the requirements of section 145.43 unless the hearing aid dispenser determines through observation or questioning that the prospective purchaser has any of six listed medical conditions.

Several comments argued that the Minnesota requirements are more stringent than the FDA requirements because, under the Minnesota law, anyone over the age of 60 and anyone with one of the listed medical conditions is required to be examined by an audiologist or a physician while, under the FDA regulation, such a person may waive medical evaluation and thus not be examined by either a physician or an audiologist.

To compare the Minnesota and FDA requirements properly, it is necessary to compare them as they apply to three categories of persons:

a. Persons under the age of 18. The Minnesota statute requires that persons under the age of 18 be examined by a physician or an audiologist and does not permit a waiver of this requirement. The FDA regulation requires that a prospective hearing aid purchaser under the age of 18 be examined by a physician and does not permit a waiver of this requirement. Because it permits examination by either a physician or an audiologist, the Minnesota requirement is less stringent than the FDA requirement.

b. Adults, age 18 to 59, who do not have any of the listed medical conditions. The Minnesota law requires these persons to be examined by a physician or an audiologist and allows a waiver of this requirement. The FDA regulation requires examination by a physician and allows a waiver of this requirement. Again, because it permits examination by either a physician or an audiologist, the Minnesota requirement

is less stringent than the FDA requirement.

c. Adults over the age of 60 or a person with any of the listed medical conditions. The Minnesota statute requires these persons to be examined by a physician or an audiologist and does not allow a waiver of this requirement. The FDA regulation requires examination by a physician but allows a waiver of this requirement. As applied to these persons, it can be argued that the Minnesota requirement is both more and less stringent than the FDA requirement.

FDA is denying exemption from preemption for sections 145.43 and 145.44. The requirement is less stringent than the FDA regulation because it allows examination by an audiologist as an alternative to examination by a physician. The agency believes that examination by an audiologist, rather than a licensed physician, will not ensure proper diagnosis of the organic causes of hearing loss. FDA is also denying exemption from preemption for this requirement because it does not permit certain adults to waive the requirement of audiological or medical examination and, therefore, would conflict with the religious and personal convictions of some people. Thus, the agency rejects the comments and in § 808.73 denies exemption from preemption for both Minnesota Statutes, sections 145.43 and 145.44.

Mississippi

28. Mississippi Code section 73-14-3(g)(9) permits the sale of a hearing aid to a child under the age of 10 upon the recommendation of an audiologist alone. One comment opposed FDA's proposal to deny exemption from preemption for this section, arguing that this requirement is necessary to protect the children of Mississippi.

FDA is denying exemption from preemption for this section because it is less stringent than the FDA requirements in that it would permit audiological evaluation as an alternative to medical evaluation for a child under the age of 10. Therefore, the agency is issuing § 808.73 as proposed.

Nebraska

29. FDA proposed to exempt from preemption Nebraska Revised Statutes 71-4712(2)(c), paragraphs (vi) and (vii). Paragraph (vi) prohibits the sale of a hearing aid to a child under the age of 16 who has not been cleared for hearing aid use by an otolaryngologist within a 6-month period. Paragraph (vii) prohibits the sale of a hearing aid to any person who has a significant air-bone gap or a unilateral sensorineural hearing loss

unless the person has been examined by an otolaryngologist within a 6-month period or has signed a statement waiving this examination.

Comments supporting the proposed exemptions stated that physicians other than otolaryngologists are not sufficiently knowledgeable about the causes of hearing loss to be able to conduct an adequate examination. Opposing comments stated that all physicians are capable of making at least an initial determination as to the cause of hearing loss and can be expected to refer the patient to an otolaryngologist when necessary. Some of these comments also pointed out that otolaryngologists are not readily available in all areas and, consequently, that this requirement could create an unnecessary burden on prospective hearing aid users.

FDA believes that examination by an otolaryngologist is not necessary in all the cases for which it is required by the Nebraska statute. Also, this requirement could create an unnecessary burden on persons wishing to use a hearing aid. FDA does not believe that examination by an otolaryngologist will provide any special benefit to an adult with a significant air-bone gap or a unilateral sensorineural hearing loss. FDA does believe, however, that hearing loss in children can be treated medically or surgically more often than it can be in adults and that otolaryngologists are more knowledgeable about such treatment than are other physicians. FDA believes, therefore, that the possible benefit to children from such a requirement outweighs the possible burden of locating an otolaryngologist. As a result, FDA is granting an exemption from preemption for paragraph (vi) but is denying exemption from preemption for paragraph (vii).

New Jersey

30. FDA is granting an exemption from preemption for New Jersey Statutes Annotated (N.J.S.A.) section 45:9A-24, which requires hearing aid dispensers to advise in writing a prospective purchaser who has any of six listed medical conditions to consult a physician. The section also requires the hearing aid dispenser to provide the prospective purchaser with the names and addresses of at least three local physicians specializing in diseases of the ear. Comments on these types of provisions are discussed in paragraph 13 above. FDA is also exempting from preemption section 45:9A-25, which prohibits the sale of a hearing aid to a person under 18 years of age unless a recommendation for a hearing aid has been made by either an otolaryngologist or an audiologist following examination and diagnosis by an otolaryngologist. Comments on these types of requirements are discussed in paragraph 13 above.

31. In the October 20, 1978 notice, FDA proposed to deny exemption from preemption for Chapter 3, Section 5 of the rules and regulations adopted pursuant to N.J.S.A. 45:9A-1 et seq. Chapter 3, Section 5 provides that no hearing aid may be sold without a hearing examination including, at a minimum, pure tone air conduction and bone conduction thresholds. The section requires that this examination be conducted in an environment that meets or exceeds the American National Standards Criteria for Background Noise in Audiometer Rooms (A.N.S.I. S3.1-1971).

Comments supporting FDA's proposal to deny exemption from preemption for this provision agreed that the provision is unnecessarily restrictive because few existing test rooms meet the A.N.S.I. standard and it has not been shown that it is necessary to use a room complying with the standard to ensure proper testing. Comments opposing the proposed denial of exemption from preemption stated that testing before the sale of a hearing aid is absolutely essential and a soundproof environment is necessary for proper testing.

Although FDA agrees that testing is necessary before the sale of a hearing aid, it does not believe that testing requirements should be unnecessarily restrictive. FDA believes it is reasonable to require that a hearing examination include air conduction and bone conduction thresholds. The requirement that the testing be conducted in an environment that meets the A.N.S.I. standard, however, is unnecessarily restrictive because it has not been shown that such an environment is necessary for proper testing. Therefore, FDA is exempting this section from preemption except for the portion requiring that the testing environment meet the A.N.S.I. standard.

New Mexico

32. FDA is granting an exemption from preemption for New Mexico Statutes Annotated, section 67-36-16(F), which prohibits the sale or fitting of a hearing aid for a person under 16 years of age who has not been examined by both an otolaryngologist and an audiologist. This provision is more stringent than the FDA requirement and will provide additional protection for the hearing health of children. Comments on this type of provision are discussed in paragraph 13 above. Thus, § 808.81, exempting this provision, is issued as proposed.

New York

33. FDA is granting exemption from preemption for section 784(3) of the General Business Law of New York and its implementing regulations, sections 191.10 and 191.11(a). These provisions require the hearing aid dispenser to give the purchaser an itemized receipt containing certain information and

require that the packaging of the hearing aid contain certain information. Comments on these types of provisions are discussed in paragraph 17 above.

In the preamble to the proposed regulation, FDA stated that section 784(4) (incorrectly identified there as section 785-a(4)), which requires the dispenser to give the purchaser a 30-day money-back written guarantee, was not preempted because it is a consumer protection provision beyond the scope of § 801.421 of the FDA regulations. The State of New York has pointed out, however, that a New York court has declared this section to be preempted by the FDA regulations and, consequently, New York cannot enforce section 784(4) unless FDA grants it an exemption.

FDA still believes that consumer protection provisions of this type are not preempted by section 521 of the act because they do not relate to the safety or effectiveness of hearing aids. However, because the State of New York cannot enforce this requirement without an exemption, the agency is granting section 784(4) an exemption from preemption. FDA believes that return privileges will encourage reluctant hearing-impaired persons to try a hearing aid and will reduce problems associated with misvaluation of hearing loss. The agency is also granting exemption from preemption for the implementing regulations, sections 191.11(b) through (e).

34. Several comments disagreed with FDA's proposal to deny exemption from preemption for section 784.1 and its implementing regulations, sections 191.6, 191.7, 191.8, and 191.9. Section 784.1 permits the sale of a hearing aid on the recommendation of either an otorhinolaryngologist or a licensed audiologist. The State of New York objected that FDA failed to consider its request that FDA exempt the following requirements of section 784.1 and its implementing regulations: (1) The requirement that the purchaser obtain a written statement from a medical ear specialist recommending the use of a hearing aid; (2) the requirement that the written statement from the medical ear specialist include the results of a pure tone and special audiometric tests and that the hearing aid be dispensed in accordance with the results of these tests; (3) the provision that the written statement from the medical ear specialist may include directions as to the type and characteristics of the appropriate hearing aid and the requirement that, where included, these directions must be followed by the dealer in dispensing the aid; (4) the provision permitting the dealer to accept a written statement from a medical doctor other than a medical ear specialist only if such a specialist is unavailable; and (5) the provision permitting a prospective purchaser to

waive the required written statement only because of religious objections.

FDA is denying exemption from preemption for all the provisions of section 784.1 because the section would allow hearing aids to be sold on the basis of an audiologist's recommendation without an examination by a physician. As stated in paragraph 10 of this preamble, the agency does not believe that examination by an audiologist is sufficient to ensure proper diagnosis of possible organic causes of hearing loss. FDA is also denying exemption from preemption for each of the provisions of section 784.1 because they permit waiver of the requirement of a medical examination only if the prospective purchaser objects to the evaluation for religious reasons. Comments on this type of provision are discussed in paragraph 14 above.

Ohio

35. FDA is granting exemption from preemption for Ohio Revised Code section 4747.09 to the extent that it requires the hearing aid dealer or fitter to give the purchaser a receipt containing certain information. Comments on these types of provisions are discussed in paragraph 17 above. The agency is denying exemption from preemption for this section, however, to the extent that it permits the parent or guardian of a child 16 years of age or under to waive the requirement that the child be examined by an otolaryngologist. This is consistent with the discussion in the preamble to the proposed regulation. In the codified portion of the proposal, however, some lines were accidentally deleted in the printing of § 808.85. The final regulation corrects this error.

Oregon

36. As proposed, FDA is denying exemption from preemption for Oregon Revised Statutes (O.R.S.) section 694.136(6) and (7) because these provisions would permit the parent or guardian of a child to waive the requirement that the child obtain a medical evaluation.

FDA is granting an exemption from preemption for the provisions of O.R.S. 694.036. This section requires the dispenser to give the purchaser a receipt containing certain information. FDA is exempting this section from preemption on the condition that, when enforcing this provision, Oregon use the definition of "used hearing aid" contained in the FDA regulation. This condition is applied to similar provisions of other States, but was not included in proposed § 808.87. The final § 808.87 has been revised to include this condition. Comments on this type of provision are discussed in paragraph 17 above.

Pennsylvania

37. FDA is denying exemption from preemption for 35 Purdon's Statutes 6700, section 402, because it does not permit a waiver of medical evaluation when certain medical conditions are found to exist. Comments on this type of provision are discussed in paragraph 15 above.

38. In the preamble to the proposal, FDA concluded that section 403 of the Pennsylvania law is not preempted. That section requires prospective hearing aid users to obtain medical clearance within 6 months before the sale of a hearing aid and permits an informed adult to waive this requirement. One comment disagreed with the agency's conclusion, arguing that the waive statement in section 403 is not identical to that required by § 801.421(a)(2)(iii) (21 CFR 801.421(a)(2)(iii)) and that hearing aid dispensers cannot comply with both requirements. One comment noted that FDA failed to include section 403 in the list of exempted provisions in proposed § 808.88.

Although the waiver statement required by section 403 is not identical to that required by the FDA regulation, it is substantially identical to the Federal requirement and, therefore, compliance with the Pennsylvania requirement would constitute compliance with the FDA requirement. The agency notes, however, that while section 403 does not apply to the sale of a replacement for a worn-out or damaged hearing aid, the FDA requirement of medical evaluation does apply to such sales. Because section 403 is not preempted, it is not necessary to include it in § 808.88, which lists the Pennsylvania requirements that are preempted and states whether they are granted or denied an exemption from preemption. Thus, the final rule has not been changed to include a reference to section 403.

39. FDA is exempting from preemption section 506, which prohibits the sale of a hearing aid to a person 18 years of age or younger unless a recommendation has been made by an otolaryngologist or otologist. Comments on this type of provision are discussed in paragraph 13 above.

FDA is also granting exemption from preemption for section 507(2), which requires that the physician's written recommendation and any signed waiver statements be kept on file for 7 years. FDA proposed to exempt this section from preemption because it is more stringent than the FDA requirement and will assist Pennsylvania in enforcing its statute. FDA received no adverse comments on its proposal to exempt this section from preemption.

Texas

40. FDA is denying exemption from preemption for Vernon's Civil Statutes,

Article 4566, section 14(d), which requires only that the hearing aid dispenser recommend that a child 10 years of age or under be examined by an otolaryngologist but does not require that the child receive a medical examination. This type of provision is addressed in paragraph 28 above.

FDA is granting exemption from preemption for section 14(b) of Article 4566, which requires the dispenser to give the purchaser a bill of sale containing certain information. FDA is exempting this section from preemption on the condition that, when enforcing these provisions, Texas apply the definition of "used hearing aid" contained in the FDA regulation. This type of provision is addressed in paragraph 17 above.

Washington

41. FDA is granting exemption from preemption for Revised Code of Washington (R.C.W.) section 18.35.110(2)(e)(i), which requires the hearing aid dispenser to advise a prospective purchaser in writing to consult with a licensed physician if any of certain listed medical conditions are found to exist. Comments on this type of provision are discussed in paragraph 16 above.

42. The agency is also granting exemption from preemption for R.C.W. section 18.35.110(2)(e)(iii), which requires the hearing aid dispenser to advise a parent or guardian of a person under 18 years of age to consult a clinical audiologist. The agency is denying exemption from preemption, however, for R.C.W. section 18.35.110(2)(e)(ii), which permits the parent or guardian of a person under 18 years of age to waive the medical evaluation requirement for the child.

West Virginia

43. FDA is denying exemption from preemption for West Virginia Code section 30-26-14(a), which requires that the prospective purchaser of a hearing aid be examined by a physician and does not permit a waiver of this requirement. Comments on this type of provision are discussed in paragraph 14 above.

The agency is granting exemption from preemption for section 30-26-14(b), which requires the hearing aid dispenser to advise a prospective purchaser in writing to consult a physician if any of six listed medical conditions are found upon examination of the person. Comments on this type of provision are discussed in paragraph 16 above.

The agency is also exempting from preemption section 30-26-14(c), which requires hearing aid dispensers to maintain certain records for 7 years. FDA is exempting this section from preemption because it is more stringent than the FDA requirement and will assist West Virginia in enforcing its statute.

In the preamble to the proposed regulation, FDA indicated its intent to exempt paragraphs (b) and (c) from preemption. However, proposed § 808.98 did not refer to these sections. The final regulation has been revised to exempt from preemption paragraphs (b) and (c).

District of Columbia

44. In proposed § 808.101, FDA proposed to grant exemption from preemption for section 5 of Act 2-79 of the District of Columbia to the extent that it requires medical clearance by an otolaryngologist within 3 months before the sale of a hearing aid and to the extent that it requires a hearing test evaluation for children under the age of 18. FDA proposed to deny exemption from preemption for this section to the extent that it permits a waiver of the medical clearance requirement for religious reasons only and to the extent that it requires a hearing test evaluation for persons 18 years of age or older.

Several comments supported granting exemption from preemption to all the provisions of section 5. Some comments noted that section 5 is the most stringent State or local law applicable to hearing aids. Other comments pointed out that there is no shortage of audiologists in this urbanized area, and, therefore, there is less reason to deny exemption from preemption for this provision. Some comments opposing the proposed exemption of certain provisions of section 5 stated that the requirements that the medical clearance be obtained from an otolaryngologist and that it be obtained within 3 months before the sale of a hearing aid are unnecessarily restrictive because any licensed physician is qualified to give medical clearance and 3 months is an unreasonably short time. Other general comments discussed above under the headings "Audiological Evaluation" and "Waiver" are applicable to section 5 and are responded to there.

FDA agrees that section 5 is unnecessarily restrictive in requiring medical clearance by an otolaryngologist within 3 months before the sale of a hearing aid. Any licensed physician is qualified to give medical clearance for a hearing aid purchase or to refer the patient to a specialist if necessary. FDA believes that it is unnecessary to require that medical clearance be obtained 3 months before the sale. Therefore, the agency is denying exemption from preemption for these portions of section 5 as well as the requirement of audiological evaluation for adults and the waiver provision. As a result, the agency is denying exemption from preemption for all of section 5 except the requirement of audiological evaluation for children under the age of 18.

As proposed, the agency is also

granting a conditional exemption for section 6 of Act 2-79, a disclosure requirement for the purchasers of hearing aids. Comments on this type of provision are discussed in paragraph 17 above.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 521, 701, 52 Stat. 1055-1056 as amended, 90 Stat. 574 [21 U.S.C. 360k, 371]) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Part 808 is amended as follows:

1. In § 808.1 by adding new paragraph (f), to read as follows:

§ 808.1 Scope.

(f) The Federal requirement with respect to a device applies whether or not a corresponding State or local requirement is preempted or exempted from preemption. As a result, if a State or local requirement that the Food and Drug Administration has exempted from preemption is not as broad in its application as the Federal requirement, the Federal requirement applies to all circumstances not covered by the State or local requirement.

2. By adding new §§ 808.53, 808.55, 808.57, 808.59, 808.67, 808.69, 808.73, 808.74, 808.77, 808.80, 808.81, 808.82, 808.85, 808.87, 808.88, 808.93, 808.97, 808.98, and 808.101, to read as follows:

§ 808.53 Arizona.

The following Arizona medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them exemptions from preemption under section 521(b) of the act:

(a) Arizona Revised Statutes, Chapter 17, sections 36-1901.7(s) and 36-1901.7(t).

(b) Arizona Code of Revised Regulations, Title 9, Article 3, sections R9-16-303 and R9-16-304.

§ 808.55 California.

(a) The following California 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: Business and Professions Code, sections 3365 and 3365.6.

(b) The following California medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Health and Safety Code, section 26463(m), as applied to hearing aids.

§ 808.57 Connecticut.

The following Connecticut medical device requirements are enforceable notwithstanding section 521(a) of the act because the Food and Drug

Administration has exempted them from preemption under section 521(b) of the act: Connecticut General Statutes, sections 20-403 and 20-404.

§ 808.59 Florida.

The following Florida medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them an exemption from preemption under section 521(b) of the act:

(a) Florida Statutes, section 468.135(5).

(b) Florida Administrative Code, section 10D-48.25(26).

§ 808.67 Kentucky.

The following Kentucky medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Kentucky Revised Statutes, section 334.200(1).

§ 808.69 Maine.

(a) The following Maine 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: Maine Revised Statutes Annotated, Title 32, section 1658-C, on the condition that, in enforcing this requirement, Maine apply the definition of "used hearing aid" in § 801.420(a)(6) of this chapter.

(b) The following Maine medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Maine Revised Statutes Annotated, Title 32, section 1658-D and the last sentence of section 1658-E.

§ 808.73 Minnesota.

The following Minnesota medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them an exemption from preemption under section 521(b) of the act: Minnesota Statutes, sections 145.43 and 145.44.

§ 808.74 Mississippi.

The following Mississippi medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Mississippi Code, section 73-14-3(g)(9).

§ 808.77 Nebraska.

(a) The following Nebraska 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: Nebraska Revised Statutes, section 71-4712(2)(c)(vi).

(b) The following Nebraska medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Nebraska Revised Statutes, section 71-4712(2)(c)(vii).

§ 808.80 New Jersey.

(a) The following New Jersey medical device requirements are enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted them from preemption under section 521(b) of the act:

(1) New Jersey Statutes Annotated, section 45:9A-23 on the condition that, in enforcing this requirement, New Jersey apply the definition of "used hearing aid" in § 801.420(a)(6) of this chapter;

(2) New Jersey Statutes Annotated, sections 45:9A-24 and 45:9A-25;

(3) Chapter 3, Section 5 of the Rules and Regulations adopted pursuant to New Jersey Statutes Annotated 45:9A-1 et seq. except as provided in paragraph (b) of this section.

(b) The following New Jersey medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Chapter 3, Section 5 of the Rules and Regulations adopted pursuant to New Jersey Statutes Annotated 45:9A-1 et seq. to the extent that it requires testing to be conducted in an environment which meets or exceeds the American National Standards Institute S3.1 Standard.

§ 808.81 New Mexico.

The following New Mexico 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: New Mexico Statutes Annotated, section 67-36-16(F).

§ 808.82 New York.

(a) The following New York medical device requirements are enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted them from preemption under section 521(b) of the act:

(1) General Business Law, Article 37, sections 784(3) and (4).

(2) Official Compilation of Codes, Rules and Regulations of the State of New York, Chapter V, Title 19, Subchapter G, section 191.10 and section 191.11(a) on the condition that, in enforcing these requirements, New York apply the definition of "used hearing

aid" in § 801.420(a)(6) of this chapter and section 191.11(b), (c), (d), and (e).

(b) The following New York medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them an exemption from preemption under section 521(b) of the act:

(1) General Business Law, Article 37, section 784.1.

(2) Official Compilation of Codes, Rules and Regulations of the State of New York, Chapter V, Title 19, Subchapter G, sections 191.6, 191.7, 191.8, and 191.9.

§ 808.85 Ohio.

(a) The following Ohio 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: Ohio Revised Code, section 4747.09, the first two sentences with respect to disclosure of information to purchasers on the condition that, in enforcing these requirements, Ohio apply the definition of "used hearing aid" in § 801.420(a)(6) of this chapter.

(b) The following Ohio medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Ohio Revised Code, section 4747.09, the last two sentences with respect to medical examination of children.

§ 808.87 Oregon.

(a) The following Oregon medical device requirements are enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted them from preemption under section 521(b) of the act: Oregon Revised Statutes, section 694.036 on the condition that, in enforcing this requirement, Oregon apply the definition of "used hearing aid" in § 801.420(a)(b) of this chapter.

(b) The following Oregon medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them exemptions from preemption under section 521(b) of the act: Oregon Revised Statutes, sections 694.136(6) and (7).

§ 808.88 Pennsylvania.

(a) The following Pennsylvania medical device requirements are enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted them from preemption under section 521(b) of the act: 35 Purdon's Statutes 6700, section 504(4) on the condition that, in enforcing this requirement, Pennsylvania apply the definition of

"used hearing aid" in § 801.420(a)(6) of this chapter; section 506; and, section 507(2).

(b) The following Pennsylvania medical device requirement is preempted by section 521(a) of the act and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: 35 Purdon's Statutes 6700, section 402.

§ 808.93 Texas.

(a) The following Texas 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: Vernon's Civil Statutes, Article 4566, section 14(b) on the condition that, in enforcing this requirement, Texas apply the definition of "used hearing aid" in § 801.420(a)(6) of this chapter.

(b) The following Texas medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Vernon's Civil Statutes, Article 4566, section 14(d).

§ 808.97 Washington.

(a) The following Washington 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: Revised Code of Washington 18.35.110(2)(e) (i) and (iii) on the condition that it is enforced in addition to the applicable requirements of this chapter.

(b) The following Washington medical device requirements are preempted by section 521(a) of the act, and the Food and Drug Administration has denied them an exemption from preemption under section 521(b) of the act: Revised Code of Washington 18.35.110(2)(e)(ii).

§ 808.98 West Virginia.

(a) The following West Virginia medical device requirements are enforceable notwithstanding section 521(a) of the act because the Food and Drug Administration has exempted them from preemption: West Virginia Code, section 30-26-14 (b) and (c).

(b) The following West Virginia medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: West Virginia Code, section 30-26-14(a).

§ 808.101 District of Columbia.

(a) The following District of Columbia medical device requirement is enforceable notwithstanding section 521 of the act because the Food and Drug

Administration has exempted it from preemption under section 521(b) of the act: Act 2-79, section 6, on the condition that, in enforcing section 6(a)(5), the District of Columbia apply the definition of "used hearing aid" in § 801.420(a)(6) of this chapter.

(b) The following District of Columbia medical device requirement is preempted by section 521(a) of the act and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Act 2-79, section 5.

Effective: November 10, 1980.

(Secs. 521, 701, 52 Stat. 1055-1056 as amended, 90 Stat. 574 (21 U.S.C. 360k, 371))

Dated: October 5, 1980.

Jere E. Goyan,

Commissioner of Food and Drugs.

[FR Doc. 80-31535 Filed 10-9-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 812

[Docket No. 76N-0324]

Medical Devices; Investigational Device Exemptions; OMB Approval and Effective Dates; Correction

AGENCY: Food and Drug Administration.

ACTION: Final rule; correction.

SUMMARY: In FR Doc. 80-26969 appearing at page 58841 in the Federal Register of Friday, September 5, 1980, the following correction is made: Docket number "76N-0327" in the heading of the document should read "76N-0324".

FOR FURTHER INFORMATION CONTACT: Agnes Black, Federal Register Writer (HFC-11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-2994.

Dated: October 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-31449 Filed 10-9-80; 8:45 am]

BILLING CODE 4110-03-M

NAVAJO AND HOPI INDIAN RELOCATION COMMISSION

25 CFR Part 700

Commission Operations and Relocation Procedures; Adoption of Regulations Regarding "Application for Life Estate Leases"

AGENCY: Navajo and Hopi Indian Relocation Commission.

ACTION: Final rule.

SUMMARY: The Commission is issuing a final rule governing the application for Life Estate Leases by members of the Navajo and Hopi Tribes who are subject to relocation. These regulations set forth application procedures as required by

the Navajo and Hopi Indian Relocation Amendments Act of 1980, 25 U.S.C. 640-d, 94 Stat. 929, Pub. L. 96-305, Sec. 30(b) (hereinafter, "the Amendments Act").

EFFECTIVE DATE: October 10, 1980.

FOR FURTHER INFORMATION CONTACT: Paul M. Tessler, CFR Liaison Officer, Navajo and Hopi Indian Relocation Commission, P.O. Box KK, Flagstaff, AZ 86002, Telephone No.: (602) 779-3311, ext. 1376, FTS: 261-1376.

SUPPLEMENTARY INFORMATION: On September 8, 1980, there was published in the Federal Register (45 FR No. 175, p. 59175), a notice of proposed standards and procedures to govern the awarding of Life Estate Leases to members of the Navajo and Hopi Tribes who are subject to relocation under Pub. L. 93-531, (25 U.S.C. 640-d). The proposed rules set forth procedures concerning the filing of applications for Life Estate Leases, definition of the term "disability", determinations of disability, and the grouping and awarding of Life Estate Leases.

The Commission has determined that because of the time limits imposed by the Amendments Act and because it has received a significant amount of comment indicating the need for further input and discussion, it would be appropriate to await adoption of rules concerning the definition of the term "disability", rating of disability, and the grouping and awarding of Life Estate Leases. Proposed rules concerning these issues and other issues such as Fencing of Life Estates, Access to Life Estates by Visitors and Family, Appeal Procedures, the Issuance of Life Estate Leases, Residency on Life Estates, Physical Examinations, and Approval Physicians, will be addressed in proposed rules to be published in November, 1980.

The Commission will therefore promulgate in this notice, only final rules concerning the application for Life Estate Leases and will limit discussion of that comment received which is relevant to this issue.

Discussion of Comments

Comment was received in two forms: Formal, written comment and via a public hearing held in Tuba City, Navajo Nation, Arizona. Seventeen (17) persons gave comment at the public hearing which was attended by approximately thirty (30) persons. Again, only that comment relevant to application for Life Estate Leases will be discussed.

1. The Hopi Tribe commented as follows: (a) That the regulations promulgated should define the procedure to be followed by applicants who desire a time extension for filing of an Application for Life Estate Lease, that such requests for extension should be written and filed before April 1, 1981,

and that both tribes should be advised of such requests and the supporting reasons given. (b) That the application should require sufficient information to establish the applicant's lawful marriage, if any, on or before July 8, 1980, and should contain the names, birthdates, marriage dates for applicant's spouse and all children. Also, other spouses, past or present, should be listed. (c) That the application should require the applicant and spouse to indicate other residences within and outside the Former Joint Use Area and whether any other family member has applied for relocation benefits. (d) That the application should require additional information such as auto titles, tax returns, bank records, etc., to demonstrate that the applicant is the "head of household". (e) That to the application should be attached a medical information release to facilitate obtaining medical records. (f) That the application should require the submission of sufficient information to demonstrate that the applicant has maintained a separate place of abode and has remained domiciled on partitioned lands continuously since December 22, 1974. (g) That the application form and procedure should clearly advise the applicant of all relocation rights and benefits he is waiving if he accepts a life estate.

Comment (a), suggesting definition of procedure to be followed by applicants who desire a time extension for filing of an Application for Life Estate Lease, was adopted and incorporated into the final rule. That portion of comment (a) suggesting that requests for extension should be received before April 1, 1981, and that both Tribes be advised of such requests, etc., was considered but not adopted.

Comment (b) was considered but not incorporated into the final rule.

Comment (c), as it suggests the listing of other residences outside the Former Joint Use Area, was adopted and incorporated into the final rule. The other portions of comment (c) were considered but not adopted.

Comment (d) was considered but not adopted. The Commission has already defined the concept of "head of household" in its Operations and Relocation Procedures, § 700.5(q).

Comment (e) was considered but not adopted. The Commission has determined that a medical information release is not necessary on the application itself. Such medical information release may be required as part of the investigative process in determining eligibility for Life Estate Leases.