(5) Advise the applicant that the pre-market notification is not required. Until the applicant receives an order declaring a device substantially equivalent, the applicant may not proceed to market the device.

(b) FDA will determine that a device is substantially equivalent to a predicate device using the following criteria:

(1) The device has the same intended use as the predicate device; and

(2) The device:

(i) Has the same technological characteristics as the predicate device; or

(ii)(A) Has different technological characteristics, such as a significant change in the materials, design, energy source, or other features of the device from those of the predicate device;

(B) The data submitted establishes that the device is substantially equivalent to the predicate device and contains information, including clinical data if deemed necessary by the Commissioner, that demonstrates that the device is as safe and as effective as a legally marketed device; and

(C) Does not raise different questions of safety and effectiveness than the predicate device.

(3) The predicate device has not been removed from the market at the initiative of the Commissioner of Food and Drugs or has not been determined to be misbranded or adulterated by a judicial order.


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

Subpart A—General Provisions

§ 808.1 Scope.

(a) This part prescribes procedures for the submission, review, and approval of applications for exemption from Federal preemption of State and local requirements applicable to medical devices under section 521 of the act.

(b) Section 521(a) of the act contains special provisions governing the regulation of devices by States and localities. That section prescribes a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and 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.

(c) Section 521(b) of the act contains a provision whereby the Commissioner...
§ 808.1 of Food and Drugs may, upon application by a State or political subdivision, allow imposition of a requirement which is different from, or in addition to, any requirement applicable under the act to the device (and which is thereby preempted) by promulgating a regulation in accordance with this part exempting the State or local requirement from preemption. The granting of an exemption does not affect the applicability to the device of any requirements under the act. The Commissioner may promulgate an exemption regulation for the preempted requirement if he makes either of the following findings:

(1) That the requirement is more stringent than a requirement under the act applicable to the device; or

(2) That the requirement is required by compelling local conditions and compliance with the requirement would not cause the device to be in violation of any applicable requirement under the act.

(d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not “requirements applicable to a device” within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

(2) Section 521(a) does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.

(3) Section 521(a) does not preempt State or local permits, licensing, registration, certification, or other requirements relating to the approval or sanction of the practice of medicine, dentistry, optometry, pharmacy, nursing, podiatry, or any other of the healing arts or allied medical sciences or related professions or occupations that administer, dispense, or sell devices. However, regulations issued under section 520(e) or (g) of the act may impose restrictions on the sale, distribution, or use of a device beyond those prescribed in State or local requirements. If there is a conflict between such restrictions and State or local requirements, the Federal regulations shall prevail.

(4) Section 521(a) does not preempt specifications in contracts entered into by States or localities for procurement of devices.

(5) Section 521(a) does not preempt criteria for payment of State or local obligations under Medicaid and similar Federal, State or local health-care programs.

(6)(i) Section 521(a) does not preempt State or local requirements respecting general enforcement, e.g., requirements that State inspection be permitted of factory records concerning all devices, registration, and licensing requirements for manufacturers and others, and prohibition of manufacture of devices in unlicensed establishments. However, Federal regulations issued under sections 519 and 520(f) of the act may impose requirements for records and reports and good manufacturing practices beyond those prescribed in State or local requirements. If there is a conflict between such regulations and State or local requirements, the Federal regulations shall prevail.

(ii) Generally, section 521(a) does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices. Where, however, such a prohibition has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, then the
prohibition will be preempted if the requirement is different from, or in addition to, a Federal requirement established under the act. In determining whether such a requirement is preempted, the determinative factor is how the requirement is interpreted and enforced by the State or local government and not the literal language of the statute, which may be identical to a provision in the act.

(7) Section 521(a) does not preempt State or local provisions respecting delegations of authority and related administrative matters relating to devices.

(8) Section 521(a) does not preempt a State or local requirement whose sole purpose is raising revenue or charging fees for services, registration, or regulatory programs.

(9) Section 521(a) does not preempt State or local requirements of the types that have been developed under the Atomic Energy Act of 1954 (42 U.S.C. 2011 note), as amended, Subchapter C—Electronic Product Radiation Control of the Federal Food, Drug, and Cosmetic Act (formerly the Radiation Control for Health and Safety Act of 1968), and other Federal statutes, until such time as the Food and Drug Administration issues specific requirements under the Federal Food, Drug, and Cosmetic Act applicable to these types of devices.

(10) Part 820 of this chapter (21 CFR part 820) (CGMP requirements) does not preempt remedies created by States or Territories of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(e) It is the responsibility of the Food and Drug Administration, subject to review by Federal courts, to determine whether a State or local requirement is equal to, or substantially identical to, requirements imposed by or under the act, or is different from, or in addition to, such requirements, in accordance with the procedures provided by this part. However, it is the responsibility of States and political subdivisions to determine initially whether to seek exemptions from preemption. Any State or political subdivision whose requirements relating to devices are preempted by section 521(a) may petition the Commissioner of Food and Drugs for exemption from preemption, in accordance with the procedures provided by this part.

(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.


§ 808.5 Advisory opinions.

(a) Any State, political subdivision, or other interested person may request an advisory opinion from the Food and Drug Administration as to whether a State or local requirement is equal to, or substantially identical to, a Federal requirement.

(b) The advisory opinion will be issued only if the Food and Drug Administration determines that the requirement is identical to a Federal requirement.

§ 808.3 Definitions.


(b) Compelling local conditions includes any factors, considerations, or circumstances prevailing in, or characteristic of, the geographic area or population of the State or political subdivision that justify exemption from preemption.

(c) More stringent refers to a requirement of greater restrictiveness or one that is expected to afford to those who may be exposed to a risk of injury from a device a higher degree of protection than is afforded by a requirement applicable to the device under the act.

(d) Political subdivision or locality means any lawfully established local governmental unit within a State which unit has the authority to establish or continue in effect any requirement having the force and effect of law with respect to a device intended for human use.

(e) State means a State, American Samoa, the Canal Zone, the Commonwealth of Puerto Rico, the District of Columbia, Guam, Johnston Reef, Midway Island, the Trust Territory of the Pacific Islands, the Virgin Islands, and Wake Island.

(f) Substantially identical to refers to the fact that a State or local requirement does not significantly differ in effect from a Federal requirement.
§ 808.20 21 CFR Ch. I (4–1–14 Edition)

Subpart B—Exemption Procedures

§ 808.20 Application.

(a) Any State or political subdivision may apply to the Food and Drug Administration for an exemption from preemption for any requirement that it has enacted and that is preempted. An exemption may only be granted for a requirement that has been enacted, promulgated, or issued in final form by the authorized body or official of the State or political subdivision so as to have the force and effect of law. However, an application for exemption may be submitted before the effective date of the requirement.

(b) An application for exemption shall be in the form of a letter to the Commissioner of Food and Drugs and shall be signed by an individual who is authorized to request the exemption on behalf of the State or political subdivision. An original and two copies of the letter and any accompanying material, as well as any subsequent reports or correspondence concerning an application, shall be submitted to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The outside wrapper of any application, report, or correspondence should indicate that it concerns an application for exemption from preemption of device requirements.

(c) For each requirement for which an exemption is sought, the application shall include the following information to the fullest extent possible, or an explanation of why such information has not been included:

(1) Identification and a current copy of any statute, rule, regulation, or ordinance of the State or political subdivision considered by the State or political subdivision to be a requirement which is preempted, with a reference to the date of enactment, promulgation, or issuance of the requirement, including hearing reports or studies concerning development or consideration of the requirement. If the requirement has been subject to any judicial or administrative interpretations, the State or political subdivision shall furnish copies of such judicial or administrative interpretations.

(2) A comparison of the requirement of the State or political subdivision and any applicable Federal requirements to show similarities and differences.
§ 808.25 Procedures for processing an application.

(a) Upon receipt of an application for an exemption from preemption submitted in accordance with §808.20, the Commissioner shall notify the State or political subdivision of the date of such receipt.

(b) If the Commissioner finds that an application does not meet the requirements of §808.20, he shall notify the State or political subdivision of the deficiencies in the application and of the opportunity to correct such deficiencies. A deficient application may be corrected at any time.

(c) After receipt of an application meeting the requirements of §808.20, the Commissioner shall review such application and determine whether to grant or deny an exemption from preemption for each requirement which is the subject of the application. The Commissioner shall then issue in the FEDERAL REGISTER a proposed regulation either to grant or to deny an exemption from preemption. The Commissioner shall also issue in the FEDERAL REGISTER a notice of opportunity to request an oral hearing before the Commissioner or the Commissioner’s designee.

(d) A request for an oral hearing may be made by the State or political subdivision or any other interested person. Such request shall be submitted to the Division of Dockets Management with- in the period of time prescribed in the notice and shall include an explanation of why an oral hearing, rather than submission of written comments only, is essential to the presentation of views on the application for exemption from preemption and the proposed regulation.

(e) If a timely request for an oral hearing is made, the Commissioner shall review such a request and may grant a legislative-type informal oral hearing pursuant to part 15 of this chapter by publishing in the FEDERAL REGISTER a notice of the hearing in accordance with §15.20 of this chapter.
The scope of the oral hearing shall be limited to matters relevant to the application for exemption from preemption and the proposed regulation. Oral or written presentations at the oral hearing which are not relevant to the application shall be excluded from the administrative record of the hearing.

(f) If a request for hearing is not timely made or a notice of appearance is not filed pursuant to §15.21 of this chapter, the Commissioner shall consider all written comments submitted and publish a final rule in accordance with paragraph (g) of this section.

(g)(1) The Commissioner shall review all written comments submitted on the proposed rule and the administrative record of the oral hearing, if an oral hearing has been granted, and shall publish in the Federal Register a final rule in subpart C of this part identifying any requirement in the application for which exemption from preemption is granted, or conditionally granted, and any requirement in the application for which exemption from preemption is not granted.

(2) The Commissioner may issue a regulation granting or conditionally granting an application for an exemption from preemption for any requirement if the Commissioner makes either of the following findings:

(i) The requirement is more stringent than a requirement applicable to the device under the act;

(ii) The requirement is required by compelling local conditions, and compliance with the requirement would not cause the device to be in violation of any requirement applicable to the device under the act.

(3) The Commissioner may not grant an application for an exemption from preemption for any requirement with respect to a device if the Commissioner determines that the granting of an exemption would not be in the best interest of public health, taking into account the potential burden on interstate commerce.

(h) An advisory opinion pursuant to §808.5 or a regulation pursuant to paragraph (g) of this section constitutes final agency action.

§ 808.35 Revocation of an exemption.

(a) An exemption from preemption pursuant to a regulation under this part shall remain effective until the Commissioner revokes such exemption.

(b) The Commissioner may by regulation, in accordance with §808.25, revoke an exemption from preemption for any of the following reasons:

(1) An exemption may be revoked upon the effective date of a newly established requirement under the act which, in the Commissioner’s view, addresses the objectives of an exempt requirement and which is described, when issued, as preemption a previously exempt State or local requirement.

(2) An exemption may be revoked upon a finding that there has occurred a change in the bases listed in §808.20(c)(4) upon which the exemption was granted.

(3) An exemption may be revoked if it is determined that a condition placed on the exemption by the regulation under which the exemption was granted has not been met or is no longer being met.

(4) An exemption may be revoked if a State or local jurisdiction fails to submit records as provided in §808.20(c)(6).

(5) An exemption may be revoked if a State or local jurisdiction to whom the exemption was originally granted requests revocation.

(6) An exemption may be revoked if it is determined that it is no longer in the best interests of the public health to continue the exemption.

(c) An exemption that has been revoked may be reinstated, upon request from the State or political subdivision, if the Commissioner, in accordance with the procedures in §808.25, determines that the grounds for revocation are no longer applicable except that the Commissioner may permit abbreviated submissions of the documents and materials normally required for an application for exemption under §808.20.
Subpart C—Listing of Specific State and Local Exemptions

§ 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(a) and 36–1901.7(t).

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

[45 FR 67336, Oct. 10, 1980]

§ 808.55 California.

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


(b) The following California medical device requirements are preempted by section 521(a) of the act, and FDA has denied them an exemption from preemption:

1. Sherman Food, Drug, and Cosmetic Law (Division 21 of the California Health and Safety Code), sections 26207, 26607, 26614, 26615, 26618, 26631, 26640, and 26641, to the extent that they apply to devices.

2. Sherman Food, Drug, and Cosmetic Law, section 26463(m) to the extent that it applies to hearing aids.


[45 FR 67324, Oct. 10, 1980]

§ 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.

[45 FR 67336, Oct. 10, 1980]

§ 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).

[45 FR 67336, Oct. 10, 1980]

§ 808.61 Hawaii.

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

1. Hawaii Revised Statutes, chapter 451A, § 14.1, subsection (a) with respect to medical examination of a child 10 years of age or under, and subsection (c).

(b) The following Hawaii 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:

1. Hawaii Revised Statutes, chapter 451A, § 14.1, subsection (a) to the extent that it requires a written authorization by a physician and does not allow adults to waive this requirement for personal, as well as religious reasons, and subsection (b).


§ 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:

Kentucky Revised Statutes, section 231.200(1).

[45 FR 67336, Oct. 10, 1980]

§ 808.69 Maine.

(a) The following Maine medical device requirement is enforceable notwithstanding section 521(a) of the act
§ 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: 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.

(b) The following Massachusetts 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: Massachusetts General Laws, Chapter 93, Section 74, except as provided in paragraph (a) of this section.

§ 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: 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;

(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 its exemption from preemption under section 521(b) of the act: New Jersey Statutes Annotated, sections 45:9A–24 and 45:9A–25;

§ 808.71 Nebraska.

(a) The following Nebraska 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: Nebraska Revised Statutes, 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.

[45 FR 67336, Oct. 10, 1980]
§ 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).

[45 FR 67337, Oct. 10, 1980]

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

(b) The following New York medical device requirements are preempted by section 521(a) of the act because the Food and Drug Administration has denied them exemptions from preemption under section 521(b) of the act: General Business Law, Article 37, 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).

[45 FR 67337, Oct. 10, 1980]

§ 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.

[45 FR 67337, Oct. 10, 1980]

§ 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, sections 694.036 on the condition that, in enforcing this requirement, Oregon apply the definition of “used hearing aid” in § 801.420(a)(6) 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.

§ 808.88 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.

§ 808.88 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).

§ 808.87 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).

§ 808.92 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, sections 30–26–14 (b) and (c) and section 30–26–15(a) on the condition that in enforcing section 30–26–15(a) West Virginia apply the definition of “used hearing aid” in §801.420(a)(6) of this chapter.

(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).

§ 808.93 District of Columbia.

(a) The following District of Columbia medical device requirements are 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 5, to the extent that it requires an audiological evaluation for children under the age of 18.

(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 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.

§ 808.95 District of Columbia.

(a) The following District of Columbia medical device requirements are 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 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.
Food and Drug Administration, HHS

2–79, section 5, except as provided in paragraph (a) of this section.

[46 FR 59236, Dec. 4, 1981]

PART 809—IN VITRO DIAGNOSTIC PRODUCTS FOR HUMAN USE

Subpart A—General Provisions

§ 809.10 Labeling for in vitro diagnostic products.

(a) The label for an in vitro diagnostic product shall state the following information, except where such information is not applicable, or otherwise specified in a standard for a particular product class or as provided in paragraph (e) of this section. Section 201(k) of the act provides that “a requirement made by or under authority of this act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information appear on the label.”

1. The proprietary name and established name (common or usual name), if any.

2. The intended use or uses of the product.

3. For a reagent, a declaration of the established name (common or usual name), if any, and quantity, proportion or concentration of each reactive ingredient; and for a reagent derived intended for common or related uses, a class may be further divided into subclasses when appropriate.

(c) [Reserved]


§ 809.4 Confidentiality of submitted information.

Data and information submitted under §809.10(c) that are shown to fall within the exemption established in §20.61 of this chapter shall be treated as confidential by the Food and Drug Administration and any person to whom the data and information are referred. The Food and Drug Administration will determine whether information submitted will be treated as confidential in accordance with the provisions of part 20 of this chapter.

[45 FR 7484, Feb. 1, 1980]

Subpart B—Labeling

§ 809.10 Labeling for in vitro diagnostic products.

(a) The label for an in vitro diagnostic product shall state the following information, except where such information is not applicable, or as otherwise specified in a standard for a particular product class or as provided in paragraph (e) of this section. Section 201(k) of the act provides that “a requirement made by or under authority of this act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information appear on the label.”

1. The proprietary name and established name (common or usual name), if any.

2. The intended use or uses of the product.

3. For a reagent, a declaration of the established name (common or usual name), if any, and quantity, proportion or concentration of each reactive ingredient; and for a reagent derived intended for common or related uses, a class may be further divided into subclasses when appropriate.

(c) [Reserved]
