

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, 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

Sec.

809.3 Definitions.

809.4 Confidentiality of submitted information.

809.5 Exemption from batch certification requirements for in vitro antibiotic susceptibility devices subject to section 507 of the act.

809.6 Conditions on the effectiveness of exemptions of antibiotic susceptibility devices from batch certification requirements.

Subpart B—Labeling

809.10 Labeling for in vitro diagnostic products.

Subpart C—Requirements for Manufacturers and Producers

809.20 General requirements for manufacturers and producers of in vitro diagnostic products.

809.30 Restrictions on the sale, distribution and use of analyte specific reagents.

AUTHORITY: 21 U.S.C. 331, 351, 352, 355, 357, 360b, 360c, 360d, 360h, 360i, 360j, 371, 372, 374, 381.

Subpart A—General Provisions

§809.3 Definitions.

(a) *In vitro diagnostic products* are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. These products

are devices as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the act), and may also be biological products subject to section 351 of the Public Health Service Act.

(b) A *product class* is all those products intended for use for a particular determination or for a related group of determinations or products with common or related characteristics or those intended for common or related uses. A class may be further divided into subclasses when appropriate.

(c) [Reserved]

(d) *Act* means the Federal Food, Drug, and Cosmetic Act.

[41 FR 6903, Feb. 13, 1976, as amended at 45 FR 7484, Feb. 1, 1980]

§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]

§809.5 Exemption from batch certification requirements for in vitro antibiotic susceptibility devices subject to section 507 of the act.

(a) Antibiotic susceptibility devices subject to section 507 of the act are exempt from the batch certification requirements of part 431 of this chapter if the following conditions are met:

(1) The antibiotic susceptibility device is approved for marketing under an appropriate antibiotic application.

(2) The antibiotic susceptibility device is packaged and labeled for dispensing in accordance with the applicable regulation (monograph) in this chapter except where other labeling has been approved in an applicable antibiotic application.

(3) The bulk antibiotic drug used in preparing the antibiotic susceptibility device meets the standards of identity, strength, quality, and purity specified

in the applicable regulation (monograph) in this chapter except where other standards have been approved in an applicable antibiotic application.

(4) The antibiotic susceptibility device meets the standards of identity, strength, quality, and purity specified in the applicable regulation (monograph) in this chapter except where other standards have been approved in an applicable antibiotic application.

(b) For each antibiotic susceptibility device subject to an exemption under this section, an approved antibiotic application is regarded to be an approved premarket approval application under section 515 of the act.

(c) Nothing in this section prevents a manufacturer from applying for batch certification of an antibiotic susceptibility device as provided in section 507(c) of the act.

(d) All exemptions from batch certification requirements for antibiotic susceptibility devices under this section are subject to the conditions of effectiveness under § 809.6.

[47 FR 39160, Sept. 7, 1982, as amended at 53 FR 11252, Apr. 6, 1988]

§ 809.6 Conditions on the effectiveness of exemptions of antibiotic susceptibility devices from batch certification requirements.

(a) If at any time after an exemption from batch certification requirements for an antibiotic susceptibility device has been granted, the Commissioner finds on the basis of new information before the agency with respect to such exempted device evaluated together with the evidence available to the agency when such exemption was granted, that certification of each batch is necessary to ensure its safety and efficacy of use, the Commissioner shall act immediately to revoke all exemptions from batch certification requirements granted for such device.

(b) If the Commissioner finds that the person granted an exemption from batch certification requirements for an antibiotic susceptibility device has failed to comply with the requirements of section 507 of the act and the regulations promulgated thereunder; or if the Commissioner finds that the requirements of § 809.5 have not been met; or if the Commissioner finds that the peti-

tion for exemption from batch certification contains any false statements of fact, the Commissioner may revoke the exemption from batch certification requirements immediately and require batch certification of the device until such person shows adequate cause why the exemption from batch certification requirements should be reinstated.

(c) If the Commissioner repeals or suspends an exemption from batch certification requirements for an antibiotic susceptibility device, a notice to that effect and the reasons therefor will be published in the FEDERAL REGISTER.

(d) Any person who contests the revocation or suspension or denial of reinstatement of an exemption from batch certification requirements for an antibiotic susceptibility device shall have an opportunity for a regulatory hearing before the Food and Drug Administration under part 16 of this chapter.

[47 FR 39160, Sept. 7, 1982]

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 also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.”

(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