

§ 433.2

are subject to the conditions of effectiveness under § 433.2.

(Approved by the Office of Management and Budget under control number 0910-0001)

[51 FR 25524, July 15, 1986; 51 FR 30478, Aug. 27, 1986, as amended at 57 FR 18001, Apr. 28, 1992]

**§ 433.2 Conditions on the effectiveness of exemptions of antibiotic drugs for human use from batch certification requirements.**

(a) If at any time an exemption from batch certification requirements for an antibiotic drug for human use has been granted, the Commissioner finds on the basis of new information before the agency with respect to such exempted drug, 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 drug.

(b) If the Commissioner finds that the person granted an exemption from batch certification requirements for an antibiotic drug for human use has failed either to comply with the requirements of section 505 of the act and the regulations promulgated thereunder or to meet the general conditions established in § 330.1 of this chapter and the conditions specified in an applicable over-the-counter drug monograph in this chapter; or if the Commissioner finds that the requirements of § 433.1 have not been met; or if the Commissioner finds that the petition 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 drug 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 drug for human use, 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 drug for human use shall have an opportunity for a regulatory hearing before the Food and Drug Administration under part 16 of this chapter.

[47 FR 39159, Sept. 7, 1982, as amended at 51 FR 25524, July 15, 1986]

**§ 433.3 Assay requirements for antibiotic drugs exempted from certification.**

(a) Certain antibiotic drugs are exempted by regulations in this chapter from the certification requirements of sections 507 and 512 of the act if such drugs comply with standards prescribed by such regulations and on condition that the label of each package bears an expiration date which is determined from the date during which the batch was last assayed and released by the manufacturer.

(b) It is the position of the Food and Drug Administration that if each batch of such exempted drugs is not tested by the manufacturer or his agent to determine whether it complies with the standards of identity, strength, quality, and purity prescribed for it, the batch is not exempt from certification and it may be deemed to be misbranded under section 502(l) of the act or be adulterated under section 501(a)(5) of the act when in interstate commerce.

**Subpart B—Exemptions for Which an Application or Notice Is Required**

**§ 433.12 Exemption for labeling.**

(a) Except as provided by paragraphs (c) and (d) of this section, a shipment or other delivery of a certifiable antibiotic drug which is to be labeled at an establishment located elsewhere than at the place of manufacture shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from the requirement of section 502(l) of the act or the certification requirements of section 512(n) of the act if the labeling of each shipping container bears the batch mark of the drug, the number of units per package

and the expiration date, and if the person who introduced such shipment or delivery into interstate commerce holds a permit (Antibiotic Form 3) from the Commissioner authorizing shipment for labeling in such establishment.

(b)(1) An application for such a permit shall be in a form specified by the Commissioner and shall give the name and location of the establishment in which such labeling is to be done.

(2) In case the applicant is the operator of such establishment, the application shall include a written agreement signed by him that he will request certification of each batch from which any shipment or delivery is made to such establishment unless it is exempt under section 801(d) of the act or §433.17; that he will not remove any of such antibiotic drug from such establishment unless it complies with section 502(l) of the act or the certification requirements of section 512(n) of the act or is so exempt, or if certification is refused, unless it is returned within a reasonable time to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured; that he will keep complete records showing the date, quantity, and batch mark of each such shipment and delivery and the disposition thereof; that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within 3 years after the date of such disposition; and that he will accord full opportunity to such officer or employee to make inventories of stocks on hand and otherwise check the correctness of such records.

(3) In case the applicant is not the operator of such establishment such application shall include or be accompanied by:

(i) A written agreement signed by the applicant that he will request certification of each batch from which any shipment or delivery is made to such establishment unless it is exempt under section 801(d) of the act or §433.17; that he will keep complete records showing the date, quantity, and batch mark of each such shipment and delivery; and that he will make such records available to any officer or

employee of the Food and Drug Administration at any reasonable hour within 3 years after the date of such shipment or delivery; and

(ii) A written agreement signed by the operator of such establishment that he will submit a request, supplemental to that of the applicant, for the certification of each batch or portion thereof comprised in any such shipment or delivery received by him unless it is exempt under section 801(d) of the act or §433.17; that he will specify in his request the number of packages of each size in such shipment or delivery, the date of delivery, the batch mark thereof, and the batch mark he will use therefor; that the batch marks to be used (if different from those of the applicant) will be only those of which the key is specified in this agreement; that the expiration date used for the batch will be only that assigned to the manufacturer by certification; that the labeling to be used for such packages will be only that of which specimens are attached to this agreement (including specimens of all brochures and other printed matter, except readily available medical publications, referred to in such labeling); that when any change is made in such key or labeling he will promptly submit to the Commissioner a full statement of such change or, in the case of changed labeling, specimens showing all such changes; that he will not remove any of such antibiotic drug from such establishment unless it complies with section 502(l) of the act or is exempt under section 801(d) of the act or §433.17 or, if certification is refused, unless it is returned within a reasonable time to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured; that he will keep complete records of the disposition of each such shipment and delivery; that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within 3 years after the date of such disposition; and that he will accord full opportunity to such officer or employee to make inventories of stocks on hand and otherwise check the correctness of such records.

(4) When the Commissioner finds that such application contains any untrue statement of a material fact or that any provision of any such agreement has been violated he may revoke such permit.

(5) Any person who contests the denial or revocation of a permit shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

(c) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is the operator of such establishment, shall become void at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof, before or after labeling, from such establishment unless such batch complies with section 502(l) of the act or the certification requirements of section 512(n) of the act or is exempt under section 801(d) of the act or §433.17 or, if certification is refused, unless such shipment or delivery is returned within a reasonable time to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured.

(d) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is not the operator of such establishment, shall expire at the beginning of the act of removing or offering to remove such shipment or delivery of any part thereof, before or after labeling from such establishment unless such batch complies with section 502(l) of the act or the certification requirements of section 512(n) of the act or is exempt under section 801(d) of the act or §433.17 or, if certification is refused, unless such shipment or delivery, within a reasonable time, is destroyed or returned to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured.

[39 FR 18939, May 30, 1974, as amended at 41 FR 48267, Nov. 2, 1976; 42 FR 15675, Mar. 22, 1977]

**§ 433.13 Exemption for manufacturing use.**

(a) Except as provided by paragraphs (c) and (d) of this section, a shipment or other delivery of any certifiable antibiotic drug subject to the regulations in this chapter that is packed in containers of not less than 10,000,000 units of penicillin or 10 grams each of one of the other antibiotic drugs shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in the establishment where it is so used, from the requirements of section 502(l) of the act or the certification requirements of section 512(n) of the act, if it conforms to the standards prescribed therefor by the section of the regulations in this chapter which is specifically applicable to such other antibiotic drug, if the label of each container bears the batch mark of the drug, the number of units or grams per package, and the date on which the latest assay of the drug was completed, and if the person who introduced each shipment or delivery into interstate commerce holds a permit from the Commissioner authorizing shipment for manufacturing use in such establishment.

(b) An application for such a permit shall be in a form specified by the Commissioner, shall give the name and location of the establishment in which such drug is to be used and shall be accompanied by:

(1) A written agreement signed by the applicant that he will keep complete records showing the date, quantity, and batch mark of each shipment and other delivery of any such drug to such establishment, and that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within 3 years after the date of such shipment or delivery;

(2) A written statement signed by the operator of such establishment showing that he has adequate facilities for the manufacture of such other drug; such statement shall contain an agreement that he will keep complete records showing the date of receipt by him and the quantity and batch mark of each such shipment and delivery and the disposition thereof and showing the quantity and batch mark of each batch