

(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

of such other drug manufactured by him 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; and

(3) A written agreement signed by the person who will own the drug after its manufacture is completed that he will request certification of each batch thereof unless it is exempt under section 801 (d) of the act or § 433.12, § 433.14, § 433.16, or § 433.17, and that he will not remove any of such 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 is returned to him for labeling.

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. 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 from such establishment, prior to its use in the manufacture of another drug, unless it is exempt under section 801(d) of the act.

(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 or any part thereof from such establishment, prior to its use in the manufacture of another

drug, unless it is exempt under section 801(d) of the act.

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§ 433.14 Exemption for storage.

(a) Except as provided by paragraphs (c) and (d) of this section, a shipment or other delivery of a drug which is to be stored at a warehouse 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 warehouse, from the requirements 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, and if the person who introduced such shipment or delivery into interstate commerce holds a permit from the Commissioner authorizing shipment for storage in such warehouse.

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

(1) A written agreement signed by the applicant that he will request certification of each batch thereof unless it is exempt under section 801(d) of the act or § 433.12, § 433.13, or § 433.16, that he will not remove any of such drug from such warehouse 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 shipment and other delivery of any such drug to such warehouse, 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

(2) A written statement signed by the operator of such warehouse showing