

sealed) is broken, or when its label or labeling is altered, mutilated, destroyed, obliterated, or removed in whole or in part, or ceases to conform to any labeling requirement prescribed by the regulations in this chapter, except that:

(i) If the drug in such container is repacked or used as an ingredient in the manufacture of another drug, and certification of the batch thus made is requested, such certificate shall continue to be effective for a reasonable time to permit certification or destruction of such batch;

(ii) If the drug is in a container packaged for dispensing and is used in compounding a prescription issued by a practitioner licensed by law to administer such drug, such certificate shall continue to be effective for a reasonable time to permit the delivery of the drug compounded on such prescription; or

(iii) If its label or labeling is removed in whole or in part for the purpose of relabeling and supplemental certification of the relabeled drug is requested, as provided by § 433.12 of this chapter.

(3) With respect to any immediate container of penicillin when it is included in the packaged combination penicillin with aluminum hydroxide gel or penicillin with a vasoconstrictor, or to any immediate container of bacitracin when it is included in the packaged combination bacitracin with a vasoconstrictor, except that when certification of the batch so included is requested, such certificate shall continue to be effective for a reasonable time to permit certification of such batch which is part of such combination;

(4) With respect to any package when the drug therein fails to meet the standards of identity, strength, quality, and purity which were in effect on the date of the certificate; except that those minor changes which occur before the expiration date and which are normal and unavoidable in good storage and distribution practice shall be disregarded.

(5) With respect to any package of a certifiable antibiotic drug subject to the regulations in this chapter, included in a packaged combination with another drug, when such other drug

fails to meet the requirements of the regulations in this chapter; or

(6) With respect to any immediate container, if such regulations require its labeling to bear a caution against dispensing otherwise than on prescription, at the beginning of the act of dispensing or offering to dispense it otherwise than:

(i) By a practitioner licensed by law to administer such drug; or

(ii) On his prescription issued in his professional practice.

§ 431.12 Certification of antibiotic drugs after shipment in bulk containers.

(a) The Food and Drug Administration has received inquiries from certain interested manufacturers concerning their shipment of certified antibiotics, packaged in bulk containers, to hospitals and pharmacies for repacking or for use in the manufacture of another drug on the order or prescription of a physician. The regulations promulgated under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357) do not prohibit the shipment of certified bulk containers of antibiotics to such persons. However, under the provisions of § 431.11(b)(2)(i), certification should be requested of each repacked batch and of each batch of another drug manufactured from such bulk drug, unless the repackaged drug or other drug has been made exempt from the certification requirements by regulation. The fact that the drug is to be repacked or manufactured on the order or prescription of a physician does not exempt it from the certification requirements of the act. Under the provisions of § 431.11(b)(2)(ii), it is only when the drug used to compound a prescription is in a container packaged for dispensing that certification of the drug so compounded is not required.

(b) In the light of these provisions, unless the manufacturer and shipper of bulk containers of antibiotics has, with the consignee, an effective permit issued under § 433.16 of this chapter, if the drug is to be repacked, or under § 433.13 of this chapter if it is to be used in the manufacture of another drug, the shipper has the responsibility of seeing that certification is requested of

each repacked batch and of each batch of another drug manufactured from such drug.

§ 431.17 Request to provide for certification of an antibiotic drug.

A request under section 507 of the Federal Food, Drug, and Cosmetic Act to provide for certification of an antibiotic drug is required to comply with the procedures and meet the requirements applicable to the submission to the Food and Drug Administration and review by the agency of applications and abbreviated applications, and amendments and supplements to them, under part 314 of this chapter.

[50 FR 7516, Feb. 22, 1985]

§ 431.20 Disposition of outdated drugs.

When certification becomes invalid because the expiration date is passed, such articles should not be disposed of for drug use either through commercial or charitable channels unless the articles have been assayed to establish potency and recertified.

Subpart B—Administrative Procedures

§ 431.50 Forms for certification or exemption of antibiotic drugs.

The following forms which must be supplied in connection with certain certification or exemption procedures for antibiotic drugs may be obtained from the Product Surveillance Branch (HFD-333), Food and Drug Administration, Department of Health and Human Services, 5600 Fishers Lane, Rockville, MD 20857.

Form

- 1 Application for exemption for storage.
- 2 Application for exemption for processing.
- 3 Application for exemption for labeling.
- 4 Application for exemption for manufacturing use.
- 7 Request for check tests and assays or certification of a batch of _____(the blank to be filled in with the name of the antibiotic drug).
- 8 Application for exemption for repackaging.
- 9 Request for supplemental certification of a batch of an antibiotic drug.

[39 FR 18934, May 30, 1974, as amended at 40 FR 28052, July 3, 1975; 41 FR 10886, Mar. 15, 1976; 50 FR 7516, Feb. 22, 1985; 50 FR 8997, Mar. 6, 1985; 55 FR 11582, Mar. 29, 1990]

§ 431.51 Suspension of certification service.

When the Commissioner finds that a person has:

- (a) Obtained or attempted to obtain a certificate through fraud or through misrepresentation or concealment of a material fact; or
- (b) Falsified the records required to be kept by § 431.61; or
- (c) Failed to keep such records or to make them available, or to accord full opportunity to take an inventory of stocks on hand, or otherwise to check the correctness of such records as required by § 431.61; or
- (d) Failed to establish a system for maintaining the records required by § 314.81 of this chapter or has repeatedly or deliberately failed to maintain such records or to make required reports in accordance with the provisions of that section, or has refused to permit access to, or copying, or verification of such records or reports; or
- (e) Failed to conform to the requirements of good manufacturing practice prescribed by parts 210, 211, 225, 226 and 229 of this chapter;

the Commissioner will immediately suspend service to such person under the regulations in this chapter. Upon request a hearing will be granted to such person to show cause why such service should be resumed.

[39 FR 18934, May 30, 1974, as amended at 40 FR 13497, Mar. 27, 1975; 55 FR 11582, Mar. 29, 1990]

§ 431.52 Hearings.

Any person who contests the suspension of certification service under § 431.51 shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

[41 FR 48267, Nov. 2, 1976, as amended at 42 FR 15675, Mar. 22, 1977]

§ 431.53 Fees.

(a) Fees for the services rendered under the regulations in this chapter shall be such as are necessary to provide, equip, and maintain an adequate certification service.