

batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that such drug as prepared by him is stable for such period of time. If the specific regulation does not stipulate an expiration period, it shall be as prescribed by this section. If the manufacturer or repacker of the drug has been exempted from the certification requirements, such date shall be the number of months after the month during which the batch was last assayed and released by the manufacturer or repacker. If an expiration date is used that is longer than the minimum date provided for the drug by specific regulations, it may be used only if the manufacturer has submitted information to the Commissioner adequate to prove that the drug is stable for such time.

(b) If it is packaged solely for manufacturing use or for repacking, each package shall bear on its outside wrapper or container and the immediate container, the following:

(1) The number of units or micrograms of activity per milligram or per gram, and the number of grams or kilograms in the immediate container.

(2) The batch mark.

(3) The statement "Caution: Federal law prohibits dispensing without prescription."

(4) The statement "For manufacturing use," "For repacking," or "For manufacturing use or repacking," and, if it is not sterile, the statement "non-sterile."

(5) The required expiration date.

(c) The expiration date prescribed for a drug by the regulations in this chapter may be omitted from the label of the immediate container if such container contains a single dose and it is packaged in an individual wrapper or container that bears the date prescribed.

[39 FR 18938, May 30, 1974, as amended at 40 FR 13497, Mar. 27, 1975]

§ 432.9 Labeling of antibiotic drugs intended for export.

(a) Antibiotic drugs subject to certification under section 507 of the act and intended for export will be certified notwithstanding failure to meet

the labeling requirements of the applicable sections if the labeling used for such drugs meets the following conditions:

(1) It has been approved before use by the Government authorities of the country to which the drugs are intended for export; and

(2) Such labeling represents that such drugs are for use only in those conditions for which they are certified for domestic distribution.

(b) The legend "Caution: Federal law prohibits dispensing without prescription" might be inappropriate on antibiotic drugs exported from the United States, since their sale may or may not be so restricted under the laws of the country of destination. The Food and Drug Administration would not object to a slight modification of the wording to read, "Caution: Federal (U.S.A.) law prohibits dispensing without prescription," by a manufacturer who wishes to market a drug under the same label both in domestic and foreign commerce.

[39 FR 18938, May 30, 1974, as amended at 40 FR 13497, Mar. 27, 1975]

§ 432.20 Declaration of potency.

Wherever the potency of an antibiotic drug included in the regulations in this chapter is expressed in terms of weight, such potency shall be equivalent to that contained in the same weight of the master standard of the drug.

[39 FR 18938, May 30, 1974, as amended at 40 FR 13497, Mar. 27, 1975]

PART 433—EXEMPTIONS FROM ANTI-BIOTIC CERTIFICATION AND LABELING REQUIREMENTS

Subpart A—General Provisions

Sec.

433.1 Exemption of antibiotic drugs for human use from batch certification requirements.

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

433.3 Assay requirements for antibiotic drugs exempted from certification.