

PART 432—PACKAGING AND LABELING OF ANTIBIOTIC DRUGS

Sec.

432.1 Packaging requirements.

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432.9 Labeling of antibiotic drugs intended for export.

432.20 Declaration of potency.

AUTHORITY: 21 U.S.C. 321, 331, 352, 353, 357, 371, 381.

CROSS REFERENCE: For other regulations in this chapter concerning antibiotic drugs exempted from certain labeling requirements, see also §201.150 of this chapter.

§432.1 Packaging requirements.

Each antibiotic drug subject to certification under section 507 or 512(n) of the act shall be packaged in immediate containers which shall be of such composition as not to cause any change in the strength, quality, or purity of the contents beyond any limits therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. The immediate containers shall be tight containers as defined by the U.S.P., except that if the antibiotic drug is dispensed as an ointment or cream, the immediate containers shall be well-closed containers as defined by the U.S.P. If the antibiotic drug is packaged for dispensing, it may be packaged in combination with a container of a suitable and harmless diluent approved by the Commissioner.

(a) If it is a sterile preparation, the containers shall be sterile at the time of filling and closing and shall be so sealed that the contents cannot be used without destroying the seal.

(b) If it is intended for parenteral use and the container is glass, it shall be transparent and colorless or light-resistant as defined by the U.S.P. The containers are closed either by fusion or by application of suitable closures, in such manner as to prevent contamination or loss of content. Multiple-dose containers are closed by a substance through which a hypodermic needle may be introduced and withdrawn without removing the closure or destroying its effectiveness. Each container shall be filled with a quantity of

a volume in excess of that designated, which excess shall be sufficient to permit the withdrawal and administration of the labeled quantity or volume, whether administered in single or multiple doses.

(c) If it is dispensed as a tablet, capsule, troche, pellet, or suppository, it may be enclosed in a foil or plastic film and such enclosure is a tight container as defined by the U.S.P., except for the provision that it shall be capable of tight reclosure. The immediate container may contain a dessicant separated from the drug by a plug of cotton or other like material.

(d) If it is dispensed as an ointment or cream, it shall be in collapsible tubes that shall in no case be larger than the 2-ounce size, except:

(1) If it is labeled for institutional use, it may be packaged in immediate containers larger than the 2-ounce size and it may be packaged in immediate containers of glass or plastic; or

(2) If it is an ointment represented for ophthalmic use, it shall be in collapsible tubes which shall not be larger than the 1/8-ounce size.

(e) If it is intended for ophthalmic use, the closure shall be one through which a hypodermic needle cannot be introduced.

[39 FR 18938, May 30, 1974, as amended at 42 FR 44225, Sept. 2, 1977; 44 FR 10377, Feb. 20, 1979]

§432.5 Labeling requirements.

(a) If an antibiotic drug is packaged for dispensing:

(1) It shall be labeled in accordance with the requirements prescribed by §201.100 of this chapter, issued under section 502(f) of the act, unless the regulations pertaining to such drug specifically exempt it from such requirements.

(2) Its labeling shall bear any additional information required for the drug by specific regulations.

(3) Each package shall bear on its outside wrapper or container and the immediate container an expiration date prescribed for the drug by specific regulations; except that in lieu of the expiration date prescribed by specific regulations, a date may be used that is 12, 18, 24, 30, 36, 42, 48, 54, or 60 months after the month during which the