

establishment where it was manufactured.

[39 FR 18939, May 30, 1974, as amended at 41 FR 48268, Nov. 2, 1976; 42 FR 15675, Mar. 22, 1977]

§ 433.17 Exemption for investigational use.

A shipment or other delivery of an antibiotic drug shall be exempt from section 502(l) of the act or the certification requirements of section 512(n) of the act if all the procedures outlined in part 312 or §511.1 of this chapter are complied with. For the purposes of this section, the references in part 312 or §511.1 of this chapter to "new drug" and "approved new animal drug application" shall be deemed to read "antibiotic drug" and "approval for certification or exemption from certification" respectively.

[39 FR 18939, May 30, 1974, as amended at 40 FR 13497, May 27, 1975; 55 FR 11582, Mar. 29, 1990]

Subpart C—Specific Use Exemptions

§ 433.20 Antibiotic drugs for isolation and differentiation of microorganisms in clinical use.

Antibiotic drugs subject to section 507 of the act shall be exempt from section 502(l) if such drugs are:

(a) Paper discs impregnated with antibiotics in the amounts listed in the following table:

Antibiotic	Content per disc
Bacitracin	0.04 unit.
Nystatin	100 units.

(b) Packaged in a container bearing on its label or labeling the following:

- (1) On the outside wrapper or container and the immediate container:
 - (i) The batch mark.
 - (ii) The potency of each disc in the batch.
 - (iii) The expiration date as prescribed under §432.5(a)(3) of this chapter.
 - (iv) The statement: Not for Susceptibility Testing.

(2) On the labeling within or attached to the package: Adequate directions for use.

§ 433.21 Antibiotics for diagnostic use.

Antibiotics packaged for the withdrawal of individually weighed portions and intended for use solely in laboratory procedures in connection with the diagnosis or treatment of disease and conspicuously so labeled shall be exempt from the certification requirements of section 502(l) and 507 of the act and the certification requirements of section 512(n) of the act if they comply with all the following conditions:

(a) The potency, moisture content, and identity comply with the standards prescribed for the antibiotic by the specific regulations issued in this chapter.

(b) It is packaged in immediate containers that are tight containers as defined by the U.S.P. Each such container shall contain not more than 1 gram.

(c) Each package bears on the label or labeling of its outside wrapper or container and the immediate container the following:

- (1) The statements "For the withdrawal of individual portions of antibiotic. Each portion must be weighed before use. Diagnostic reagent. For professional use only."
- (2) The number of milligrams or grams contained in each immediate container and the potency per milligram.
- (3) The batch mark.
- (4) The statement "Expiration date _____", the blank being filled in with the date that does not exceed the expiration date authorized for the antibiotic by this chapter.

(d) The circular or other labeling within or attached to the package bears directions adequate for the use of such drug.

CROSS REFERENCES: For tests and methods of assay and certification of antibiotics susceptibility discs for laboratory diagnosis of disease, see §§460.1 and 460.6 of this chapter.

§ 433.22 Biologic drugs that contain antibiotics as a preservative.

Biological drugs that contain any certifiable antibiotic drug subject to the regulations in this chapter, and the purpose of the antibiotic is for use only as a preservative and the biological drug is conspicuously so labeled, shall be exempt from the requirements of sections 502(l) and 507 of the act and