

the certification requirements of section 512(n) of the act, if such drugs are licensed under the Public Health Service Act of July 1, 1944 (58 Stat. 682; 42 U.S.C. 201 et seq.) or under the Virus-Serum-Toxin Act of March 4, 1913 (37 Stat. 832; 21 U.S.C. 151 et seq.).

§ 433.23 Microbiological culture media containing antibiotics.

Microbiological culture media that contain any certifiable antibiotic drug subject to the regulations in this chapter shall be exempt from the requirements of sections 502(l) and 507 of the act and the certification requirements of section 512(n) of the act if:

- (a) They are intended for use in tissue culture and the antibiotic drug is added solely for use as an aid in the prevention of microbial contamination; or
- (b) They are intended for use in the isolation of selected organisms from mixed cultures and the antibiotic drug is added solely for use as an aid in such isolation; and
- (c) The certifiable antibiotic drug used in such culture media complies with the applicable standards of identity, strength, quality, and purity prescribed therefor.

§ 433.24 Exemption of antibiotic drugs for use in teaching, law enforcement, research, and analysis.

Antibiotic drugs subject to section 507 or 512(n) of the act shall be exempt from the requirements of section 502(l) and from the certification requirements of section 512(n) of the act if shipped or sold to, or in the possession of, persons regularly and lawfully engaged in instruction in pharmacy, chemistry, or medicine not involving clinical use; or in law enforcement; or in research not involving clinical use; or in chemical analysis or physical testing, provided they are to be used only for such instruction, law enforcement, research, analysis, or testing, and provided further that their labels bear the statement "Not for drug use."

§ 433.25 [Reserved]

§ 433.26 Neomycin sulfate ointment intended for hypersensitivity testing.

Neomycin sulfate ointment subject to sections 502(l) and 507 of the act and

packaged for use as an allergen for skin patch testing of hypersensitivity shall be exempt from the certification requirements of section 502(l) and 507 of the act if it complies with all the following conditions:

- (a) It contains neomycin sulfate equivalent to 200 milligrams of neomycin per gram in petrolatum.
- (b) The neomycin sulfate used in preparing the neomycin sulfate ointment conforms to the standards prescribed by § 444.42(a)(1) of this chapter except § 444.42(a)(1)(ii).
- (c) The shipment of neomycin sulfate is made as a result of a specific request made to the manufacturer or distributor by a practitioner licensed by law to administer such drug, and the use of neomycin sulfate ointment for patch testing is not promoted by the manufacturer or distributor.
- (d) Each package shall bear on its outside wrapper or container and on the immediate container, in addition to other labeling information required by the act and regulations, the following statements in lieu of adequate directions for use:
 - (1) The statement, "Caution: Federal law prohibits dispensing without prescription".
 - (2) The statement, "For use only in patch testing".
 - (3) The potency of the ointment.
 - (4) The expiration date as prescribed by § 432.5(a)(3) of this chapter.
- (e) The quantity shipped is limited to an amount reasonable for the purpose of patch testing in the normal course of the practice of medicine and is used solely for such patch testing.
- (f) The manufacturer or distributor maintains records of all shipments for this purpose for a period of 2 years after shipment and will make them available to the Food and Drug Administration upon request.

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Subpart D—Records and Reports

§ 433.30 Records retention.

At the option of the person having control of records required to be kept by any regulation in this part 433, photostatic or other permanent reproductions may be substituted for such