Penicillin	30.0 units
Streptomycin	30.0 mcg.
Polymyxin B	30.0 mcg.
Neomycin	30.0 mcg.
Gentamicin	30.0 mcg.

(c) Permitted combinations:

(1) Penicillin and streptomycin.

(2) Either amphotericin B or nystatin, but not both, may be used with one of the other antibiotics listed in paragraph (b) of this section, or with a combination of penicillin and streptomycin, or with a combination of polymyxin B and neomycin.

(3) The maximum amount of each antibiotic in a combination shall be the amount prescribed for such antibiotic in paragraph (b) of this section.

(d) Antibiotics used in virus seed stock purification are not restricted as to kind or amounts provided carryover into the final product is controlled and specified in outlines of production.

[39 FR 16869, May 10, 1974, as amended at 56 FR 66784, Dec. 26, 1991

§ 114.11 Storage and handling.

Biological products at licensed establishments shall be protected at all times against improper storage and handling. Completed product shall be kept under refrigeration at 35 °to 45 °F. (2 °to 7 °C.) unless the inherent nature of the product makes storage at a different temperature advisable, in which case, the proper storage temperature shall be specified in the filed Outline of Production. All biological products to be shipped or delivered shall be securely packed.

§ 114.12 Expiration date required.

Each serial or subserial of biological product prepared in a licensed establishment shall be given an expiration date determined in accordance with the requirements provided in §114.13 or §114.14. A licensed biological product shall be considered worthless under the Virus-Serum-Toxin Act subsequent to the expiration date appearing on the label.

[41 FR 44687, Oct. 12, 1976]

§ 114.13 Expiration date determination.

Unless otherwise provided for in a Standard Requirement of filed Outline of Production, the expiration date for each product shall be computed from the date of the initiation of the potency test. Prior to licensure, stability of each fraction shall be determined by methods acceptable to Animal and Plant Health Inspection Service. Expiration dates based on this stability data shall be confirmed as follows:

(a) *Products consisting of viable organisms.* Each serial shall be tested for potency at release and at the approximate expiration date until a statistically valid stability record has been established.

(b) *Nonviable biological products.* Each serial presented in support of licensure shall be tested for potency at release and at or after the dating requested.

(c) Subsequent changes in the dating period for a product may be granted, based on statistically valid data submitted to support a revision of the Outline of Production.

[50 FR 24903, June 14, 1985, as amended at 56 FR 66784, Dec. 26, 1991]

§ 114.14 Extension of expiration date for a serial or subserial.

(a) Unless otherwise provided for in a filed Outline of Production for the product, the expiration date shall not be extended:

(1) If all fractions of the product are not evaluated for potency by tests designated in the filed Outline of Production for such product in accordance with §113.4(b) of this subchapter.

(2) For any serial or portion of any serial which has left licensed premises: *Provided,* That product which has been shipped from one licensed premises to another licensed premises shall be exempt from this requirement.

(3) For a serial or portion of a serial if the expiration date has been extended previously, unless otherwise authorized in accordance with §114.1.

(b) An extension of the expiration date may be granted by Animal and Plant Health Inspection Service if a request from the licensee is substantiated by valid test data which demonstrate the potency of the product meets or exceeds the requirements for release. The new expiration date shall be calculated from the date the latest satisfactory potency test was initiated. The extension of the expiration date shall not exceed the maximum dating