allowed in the filed Outline of Production.

(1) Serials are approved for redating under the condition that Animal and Plant Health Inspection Service may require the firm to retest the redated serial for potency during the extended dating period and if found unsatisfactory require it be removed from the market by the licensee.

(2) [Reserved]

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

§ 114.15 Disposal of unsatisfactory products and byproducts.

All biological products found to be unsatisfactory for marketing, all biological products which have become worthless subsequent to the expiration date, all refuse, other materials deemed unsatisfactory for production purposes, all carcasses (part or whole) of production or test animals, and any undesirable byproducts of manufacture shall be disposed of as may be required by the Administrator.

[41 FR 44687, Oct. 12, 1976, as amended at 56 FR 66784, Dec. 26, 1991]

§ 114.16 Producing subsidiaries.

A serial or subserial of a biological product may be produced jointly by a licensee and one or more subsidiaries, or by two or more subsidiaries. The exact amount of each serial or subserial credited to each participating producer shall be determined at the time of labeling and packaging and shall be noted in the records for such serial or subserial.

[40 FR 46093, Oct. 6, 1975]

§ 114.17 Rebottling of biological products.

The Administrator may authorize the rebottling of a completed product in liquid form subject to the conditions prescribed in this section.

(a) All or part of a serial which has not left the licensed establishment may be aseptically returned to the mixing tank, thoroughly mixed, and rebottled in new final containers.

(b) The rebottled product shall be adequately identified by serial number or subserial number, as the case may be.

(c) Required purity tests for final container samples of the product shall be conducted on new samples selected from the rebottled product (serial or subserials). Rebottled product found to be unsatisfactory by such tests shall not be released.

(d) New test samples from each serial or subserial and copies of test reports of all tests conducted on the rebottled product shall be submitted to Animal and Plant Health Inspection Service.

(e) The licensee shall not release the rebottled product unless notified by Animal and Plant Health Inspection Service that such product is eligible for release. Production records shall show the results of all tests conducted and shall accurately reflect the actions taken.

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

§ 114.18 Reprocessing of biological products.

The Administrator may authorize a licensee to reprocess a serial of completed product subject to the conditions prescribed in this section.

(a) Reprocessing shall not include any method or procedure which would be deleterious to the product.

(b) All appropriate tests for purity, safety, potency, and efficacy for the product shall be conducted on the reprocessed product. A serial found unsatisfactory by a required test shall not be released.

(c) The reprocessed serial shall be identified by a new serial number and the records for the serial shall accurately reflect the action taken.

(d) Test samples of the reprocessed serial and test reports for all tests conducted shall be submitted to Animal and Plant Health Inspection Service. The licensee shall not release the serial until notified by Animal and Plant Health Inspection Service that the serial is eligible for release.

[50 FR 24904, June 15, 1985, as amended at 56 FR 66784, Dec. 26, 1991]

PART 115—INSPECTIONS

Sec.