

Animal and Plant Health Inspection Service, USDA

§ 115.1

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.

115.1 Inspections of establishments.

115.2 Inspections of biological products.

AUTHORITY: 21 U.S.C. 151-159; 7 CFR 2.22, 2.80, and 371.4.

§ 115.1 Inspections of establishments.

(a) Any inspector shall be permitted to enter any establishment where any biological product is prepared, at any hour during the day or night, and shall be permitted to inspect, without previous notification, the entire premises of the establishment, including all buildings, compartments, and other places, all biological products, and organisms and vectors in the establishment, and all materials and equipment, such as chemicals, instruments, apparatus, and the like, and the methods used in the manufacture of, and all records maintained relative to, biological products produced at such establishment.

(b) Each inspector will have in his or her possession a numbered USDA badge or identification card. Either shall be sufficient identification to entitle him/her to admittance at all regular entrances and to all parts of such establishment and premises and to any place at any time for the purpose of making an inspection pursuant to paragraph (a) of this section.

[52 FR 30134, Aug. 13, 1987]

§ 115.2 Inspections of biological products.

Any biological product, the container of which bears a United States veterinary license number or a United States veterinary permit number or other mark required by these regulations may be inspected at any time or place. If, as a result of such inspection, it appears that any such product is worthless, contaminated, dangerous or harmful, the Secretary shall give notice thereof to the manufacturer or importer and to any jobbers, wholesalers, dealers or other persons known to have any of such product in their possession, and may proceed against such product pursuant to the provisions of part 118 of this subchapter. Unless and until the Secretary shall otherwise direct, no persons so notified shall thereafter sell, barter, or exchange any such product in any place under the jurisdiction of the United States or ship or deliver for shipment any such product in or from any State, Territory, or the District of Columbia. However, failure to receive such notice shall not excuse any person from compliance with the Virus-Serum-Toxin Act.

[52 FR 30134, Aug. 13, 1987]

PART 116—RECORDS AND REPORTS**Sec.**

- 116.1 Applicability and general considerations.
- 116.2 Inventory and disposition records.
- 116.3 Label records.
- 116.4 Sterilization and pasteurization records.
- 116.5 Reports.
- 116.6 Animal records.
- 116.7 Test records.
- 116.8 Completion and retention of records.

AUTHORITY: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

§ 116.1 Applicability and general considerations.

(a) Each licensee, permittee, and foreign manufacturer of biological products imported into the United States shall maintain, at the licensed or foreign establishment in which the products are prepared, detailed records of information necessary to give a complete accounting of all the activities within each establishment. Such

records shall include, but shall not be limited to, the items enumerated in this part.

(1) Records shall be made concurrently with the performance of successive steps in the development and preparation of biological products, including new products under development. Such records shall include the date and where critical, the time that each essential step was taken, the identity and quantity of ingredients added or removed at each step, and any gain or loss of product from the beginning to the end of product preparation.

(2) Records shall be legible and indelible; shall be as detailed as necessary for a clear understanding of each step by one experienced in the preparation of biological products; and shall be verified by initials or signature of the person immediately responsible for the action taken.

(3) Records (other than disposition records) required by this part shall be completed by the licensee or the foreign manufacturer, as the case may be, before any portion of a serial of any product shall be marketed in the United States or exported.

(b) If, at any time, there are indications that raise questions regarding the purity, safety, potency, or efficacy of a product, or if it appears that there may be a problem regarding the preparation, testing, or distribution of a product, the licensee, permittee, or foreign manufacturer must immediately notify the Animal and Plant Health Inspection Service concerning the circumstances and the action taken, if any. Notification may be made by mail to Director, Center for Veterinary Biologics, Inspection and Compliance, 510 South 17th Street, Suite 104, Ames, IA 50010–8197; by electronic mail to cvb@usda.gov; by fax to (515) 232–7120; or by telephone to (515) 232–5785.

(c) When authorized by the Administrator, the licensee, permittee, or foreign manufacturer may maintain and retain records required under this part at an alternative location. Such authorization shall be confirmed by the filing of an addendum to the plot plan legend. The addendum shall list the location of the records and the condition of their storage and shall permit the