

§ 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