§ 115.2 Inspections of biological products.

(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.

§ 115.2 Inspections of biological products.

(a) 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 to stop distribution and sale to the manufacturer (licensee) or importer (permittee) and may proceed against such product pursuant to the provisions of part 118 of this subchapter.

(b) When notified to stop distribution and sale of a serial or subserial of a veterinary biological product by the Secretary, veterinary biologics licensees or permittees shall:

(1) Stop the preparation, distribution, sale, barter, exchange, shipment, or importation of the affected serial(s) or subserial(s) of any such veterinary biological product pending further instructions from APHIS.

(2) Immediately, but no later than 2 days, send stop distribution and sale notifications to any jobbers, wholesalers, dealers, foreign consignees, or other persons known to have any such veterinary biological product in their possession, which instruct them to stop the preparation, distribution, sale, barter, exchange, shipment, or importation of any such veterinary biological product. All notifications shall be documented in writing by the licensee or permittee.

(3) Account for the remaining quantity of each serial(s) or subserial(s) of any such veterinary biological product at each location in the distribution channel known to the manufacturer (licensee) or importer (permittee).

(4) When required by the Administrator, submit complete and accurate reports of all notifications concerning stop distribution and sale actions to the Animal and Plant Health Inspection Service pursuant to §116.5 of this subchapter.

(c) 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.

(Approved by the Office of Management and Budget under control number 0579–0318).

[72 FR 17798, Apr. 10, 2007]

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.


§ 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. Each record 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