

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; 37 Stat. 832-833.

§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.

§ 116.1

- 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 371.2(d).

§ 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) In the case of imported products, each permittee shall maintain at the permittee's place of business detailed and accurate records that are relevant to each imported product and that include, but are not limited to, importation documents, sampling records, test summaries, shipping records, and in-

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ventory and disposition records as required in § 116.2.

(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 inspection of the records by APHIS inspectors, or foreign inspectors acting on behalf of APHIS.

(Approved by the Office of Management and Budget under control number 0579-0013)

(44 U.S.C. 3506)

[39 FR 16872, May 10, 1974, as amended at 48 FR 57473, Dec. 30, 1983; 61 FR 52874, Oct. 9, 1996]

§ 116.2 Inventory and disposition records.

(a) Records shall show the quantity and location of each biological product being prepared, in storage, and in distribution channels.

(b) Detailed disposition records, in a form satisfactory to the Administrator, shall be maintained by each licensee, each distributor, and each permittee showing the sale, shipment, or other disposition made of the biological products handled by such person.

(Approved by the Office of Management and Budget under control number 0579-0013)

(44 U.S.C. 3506)

[39 FR 16872, May 10, 1974, as amended at 48 FR 57473, Dec. 30, 1983; 56 FR 66784, Dec. 26, 1991; 61 FR 52874, Oct. 9, 1996]

§ 116.3 Label records.

(a) Each licensee and permittee shall maintain a list of all approved labels currently being used. Each label shall be identified as to:

(1) Name and product code number as it appears on the product license or permit for the product;

(2) Where applicable, the size of the package (doses, ml, cc, or units) on which the label shall be used;

(3) Label number and date assigned; and

(4) Name of licensee or subsidiary appearing on the label as the producer.

(b) All labels printed shall be accounted for and an inventory maintained.

Records shall include the disposition of such labels including those not used in labeling a product.

(Approved by the Office of Management and Budget under control number 0579-0013)

(44 U.S.C. 3506)

[39 FR 16872, May 10, 1974, as amended at 48 FR 57473, Dec. 30, 1983; 61 FR 52874, Oct. 9, 1996]

§ 116.4 Sterilization and pasteurization records.

Records shall be made by means of automatic recording devices or an equivalent accurate and reliable system. Such records shall be identified with the ingredients, equipment, or biological product subjected to sterilization or pasteurization.

(Approved by the Office of Management and Budget under control number 0579-0013)

(44 U.S.C. 3506)

[39 FR 16872, May 10, 1974, as amended at 48 FR 57473, Dec. 30, 1983; 61 FR 52874, Oct. 9, 1996]

§ 116.5 Reports.

(a) When required by the Administrator, reports containing accurate and complete information concerning biological products, including but not limited to, product development and preparation, and market suspensions and recalls, shall be prepared and submitted to the Animal and Plant Health Inspection Service by the licensee, permittee, or foreign manufacturer (whose products are being imported or offered for importation). Unless otherwise authorized by the Administrator, records necessary to make such reports shall be maintained in each establishment.

(b) If, at any time, there are indications which raise questions regarding purity, safety, potency, or efficacy of a product, or if it appears that there may be a problem regarding preparation, testing, or distribution of a product, the licensee, permittee, or foreign manufacturer shall immediately notify Veterinary Biologics Field Operations, APHIS, 223 South Walnut Avenue,

Ames, Iowa 50010, concerning the circumstances and the action taken, if any. Notification may be either by mail, electronic mail, facsimile, or telephone. If by electronic mail, vbfo@aphis.usda.gov. If by facsimile, Area Code (515) 232-7120. If by telephone, Area Code (515) 232-5785.

(Approved by the Office of Management and Budget under control number 0579-0013)

[61 FR 52874, Oct. 9, 1996]

§ 116.6 Animal records.

Complete records shall be kept for all animals at a licensed establishment. Results of tests performed, antigens or treatment administered, maintenance and production records, disposition records, necropsy records, if any, and all other pertinent records shall be included.

(Approved by the Office of Management and Budget under control number 0579-0013)

(44 U.S.C. 3506)

[39 FR 16872, May 10, 1974, as amended at 48 FR 57473, Dec. 30, 1983; 61 FR 52874, Oct. 9, 1996]

§ 116.7 Test records.

Detailed records of all tests conducted on each serial and each subserial shall be maintained by the licensee. Summaries of such tests shall be prepared from such records and submitted to the Animal and Plant Health Inspection Service using APHIS Form 2008 or an acceptable equivalent form prior to release of the serial or subserial. Blank forms for such summaries shall be available from Animal and Plant Health Inspection Service upon request.

(Approved by the Office of Management and Budget under control number 0579-0013)

[39 FR 16872, May 10, 1974, as amended at 48 FR 57473, Dec. 30, 1983; 56 FR 66784, Dec. 26, 1991; 61 FR 52874, Oct. 9, 1996]

§ 116.8 Completion and retention of records.

All records (other than disposition records) required by this part shall be completed by the licensee, permittee, or foreign manufacturer before any portion of a serial of any product may be marketed in the United States or

exported. All records shall be retained at the licensed or foreign establishment or permittee's place of business for a period of two years after the expiration date of a product, or for such longer period as may be required by the Administrator.

(Approved by the Office of Management and Budget under control number 0579-0013)

[61 FR 52874, Oct. 9, 1996]

PART 117—ANIMALS AT LICENSED ESTABLISHMENTS

Sec.

- 117.1 Applicability.
- 117.2 Animal facilities.
- 117.3 Admittance of animals.
- 117.4 Test animals.
- 117.5 Segregation of animals.
- 117.6 Removal of animals.

AUTHORITY: 21 U.S.C. 151-159; 7 CFR 2.22, 2.80, and 371.2(d).

SOURCE: 38 FR 15499, June 13, 1973, unless otherwise noted.

§117.1 Applicability.

(a) All animals used in licensed establishments in the preparation or testing of biological products shall meet the regulations in this subchapter and special requirements as may be prescribed by the Administrator to prevent the preparation, sale, and distribution of worthless, contaminated, dangerous, or harmful biological products.

(b) Unless otherwise authorized or directed by the Administrator, animals used in the preparation or testing of biological products shall be admitted to and maintained at the licensed establishment and ultimately disposed of in accordance with the regulations in this part, and with the Act of August 24, 1966 (Pub. L. 89-544) as amended by the Animal Welfare Act of 1970 (Pub. L. 91-579) and the regulations in parts 1, 2, and 3 of this chapter. Personnel who supervise the care and welfare of such animals shall be qualified by education, training, and experience to carry out the regulations in this part.

[38 FR 15499, June 13, 1973, as amended at 56 FR 66784, Dec. 26, 1991]

§117.2 Animal facilities.

Animal facilities shall comply with the requirements provided in part 108 of this chapter.

§117.3 Admittance of animals.

(a) No animal which shows clinical signs or other evidence of disease shall be admitted to the premises of licensed establishments, except as provided in paragraphs (d) and (e) of this section. The health status of all animals offered for admission shall be determined by or under the direction of a veterinarian prior to admission. If the determination cannot be made prior to admission, the animals shall be kept separate from animals already on the premises and in a quarantine area to be provided by the licensee for this purpose until the animal's health status is determined.

(b) If special test requirements for admittance of the animals are specified in the Outline of Production for the product to be produced, the animals shall remain in the quarantine area until such tests have been performed and the results obtained. Animals which do not meet the requirements shall not be admitted to the production area or allowed to contact production animals.

(c) All animals admitted to the premises of a licensed establishment shall be permanently identified either collectively or individually by the licensee with tags, marks, or other means acceptable to the Administrator.

(d) When an animal which has a disease is to be used to prepare a biological product for control of such disease, the animal shall be admitted directly to the processing facilities in which the product is to be prepared but shall not be permitted contact with other animals on the premises.

(e) The Administrator may authorize the maintenance of diagnostic facilities at the licensed establishment: *Provided*, That safeguards proposed by the licensee are adequate to prevent diseased or dead animals brought into such facilities from being a threat to biological products prepared in such establishment or to other animals on the