

**§ 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.

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(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 au-

thorized 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.

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[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.

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(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

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Plant Health Inspection Service upon request.

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[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.

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[61 FR 52874, Oct. 9, 1996]

**PART 117—ANIMALS AT LICENSED ESTABLISHMENTS**

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- 117.1 Applicability.
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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 estab-

lishment 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