

PART 102—LICENSES FOR BIOLOGICAL PRODUCTS

Sec.

- 102.1 Licenses issued by the Administrator.
 102.2 Licenses required.
 102.3 License applications.
 102.4 U.S. Veterinary Biologics Establishment License.
 102.5 U.S. Veterinary Biological Product License.
 102.6 Conditional licenses.

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

§ 102.1 Licenses issued by the Administrator.

Each establishment qualified to prepare biological products under the Virus-Serum-Toxin Act shall hold an unexpired and unrevoked U.S. Veterinary Biologics Establishment License issued by the Administrator and a U.S. Veterinary Biological Product License for each product prepared in such establishment unless the product is subject to the provisions of 9 CFR parts 103 or 106 of this subchapter.

[60 FR 48021, Sept. 18, 1995]

§ 102.2 Licenses required.

(a) Every person who prepares biological products subject to the Virus-Serum-Toxin Act shall hold an unexpired, unsuspended, and unrevoked U.S. Veterinary Biologics Establishment License and at least one unexpired, unsuspended, and unrevoked U.S. Veterinary Biological Product License issued by the Administrator to prepare a biological product.

(b) An applicant who applies for an establishment license must also apply for at least one product license. An establishment license will not be issued without a license authorizing the production of a biological product in the establishment.

[52 FR 11026, Apr. 7, 1987, as amended at 56 FR 66783, Dec. 26, 1991; 61 FR 52873, Oct. 9, 1996]

§ 102.3 License applications.

(a) *U.S. Veterinary Biologics Establishment License.* (1) The operator of each establishment of the kind specified in § 102.2 shall make written application to the Administrator for a license. Blank forms of application will be fur-

nished upon request to Animal and Plant Health Inspection Service.

(2) When a person conducts more than one establishment, a separate application shall be made for each establishment.

(3) Whenever subsidiaries are to operate in an establishment for which license application is made, the applicant shall apply for permission for such subsidiaries to operate in the establishment and furnish therewith a complete statement regarding the relationship between the applicant and the subsidiaries.

(4) Facilities documents, prepared as prescribed in part 108 of this subchapter, shall accompany the application for license unless previously filed with Animal and Plant Health Inspection Service.

(5) Each application for a U.S. Veterinary Biologics Establishment License shall be accompanied by an application for one or more U.S. Veterinary Biological Product Licenses and the supporting documents required by paragraph (b)(2) of this section.

(6) A new application shall be made when a change of ownership, operation, or location of an establishment occurs; or prior to the expiration of a U.S. Veterinary Biologics Establishment License issued for an interim period of time.

(b) *U.S. Veterinary Biological Product License.* (1) The licensee of each establishment or applicant for an establishment license shall make written application to the Administrator for a U.S. Veterinary Biological Product License for each biological product to be prepared in the licensed establishment.

(2) Each application for a U.S. Veterinary Biological Product License shall be supported by:

(i) At least two copies of an Outline of Production prepared in accordance with §§ 114.8 and 114.9 of this subchapter; and

(ii) At least three copies of test reports and research data sufficient to establish purity, safety, potency, and efficacy of the product; and

(iii) Legends prepared as prescribed in § 108.5 of this subchapter designating which facilities are to be used in the preparation of each fraction; and

(iv) Labels in finished form or sketches prepared as prescribed in § 112.5 of this subchapter, together with information regarding all claims to be made on labels and in advertising matter to be used in connection with or related to the biological product.

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

[39 FR 37763, Oct. 24, 1974, as amended at 48 FR 57472, Dec. 30, 1983; 49 FR 21043, May 18, 1984; 50 FR 50763, Dec. 12, 1985; 56 FR 66783, Dec. 26, 1991; 75 FR 20772, Apr. 21, 2010]

§ 102.4 U.S. Veterinary Biologics Establishment License.

(a) Before a U.S. Veterinary Biologics Establishment License will be issued by the Administrator for any establishment, an inspection shall be made to determine whether the condition, equipment, facilities, and the like, of the establishment, and the methods used to prepare biological products are in conformity with the requirements in the regulations.

(b) A license shall not be issued unless:

(1) In the opinion of the Administrator, the condition of the establishment, including its facilities, and the methods of preparation of biological products are such as reasonably to assure that the products shall accomplish the purpose for which they are intended; and

(2) The Administrator is satisfied on the basis of information before him that:

(i) The establishment shall be operated in compliance with the Act and applicable regulations and be under the supervision of person(s) competent in the preparation of biological products; and

(ii) The applicant, or the person having the responsibility for producing biological products in the establishment, or both, is qualified by education and experience, and has demonstrated fitness to produce such products in compliance with the Act and regulations issued pursuant thereto; *Provided*, That, previous violations of the Act, or such regulations or both shall be relevant to the Administrator's determination of fitness.

(3) Written assurance is filed with Animal and Plant Health Inspection

Service that the biological products which are licensed to be prepared therein shall not be so advertised as to mislead or deceive the purchasers and that the packages or containers in which the same are to be marketed shall not bear any statement, design, or device which is false or misleading in any particular.

(c) U.S. Veterinary Biologics Establishment Licenses shall be numbered.

(d) Two or more licenses may bear the same number when they are issued for establishments under the same ownership or control, provided a serial letter is added to one or more to identify each license and the product produced thereunder.

(e) When a U.S. Veterinary Biologics Establishment License is issued for an establishment, it shall not apply to more than one person at the same location, except that subsidiaries of the licensee, when named in the license, may operate thereunder at the establishment named. The licensee with its subsidiaries will be held responsible for all operations conducted in the licensed establishment.

(f) When a licensee no longer holds at least one unexpired, unsuspended, or unrevoked product license authorizing the preparation of a biological product, or is in the process of obtaining a product license, the establishment license shall no longer be valid and shall be returned to the Administrator. In the case where an establishment license expires or is suspended or revoked, any product license authorizing preparation of a product at such establishment shall be invalid indefinitely or for as long as the suspension is in effect.

(g) Any license issued under this part to establishments in which biological products are prepared shall be issued on condition that the licensee permit the inspection of such establishments, products, product preparation, and all relevant records as provided in part 115 of this subchapter. Failure to permit inspection may result in the license being suspended or revoked.

(h) The provisions of paragraph (b) of this section shall also be applicable to,