

§ 102.4

9 CFR Ch. I (1–1–16 Edition)

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,

and be considered by, the Administrator in connection with each application for an additional product license.

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

[39 FR 37762, Oct. 24, 1974; 39 FR 38364, Nov. 1, 1974, as amended at 41 FR 44359, Oct. 8, 1976; 48 FR 57472, Dec. 30, 1983; 52 FR 11026, Apr. 7, 1987; 52 FR 30131, Aug. 13, 1987; 56 FR 66783, Dec. 26, 1991; 60 FR 48021, Sept. 18, 1995; 61 FR 52873, Oct. 9, 1996; 62 FR 13294, Mar. 20, 1997]

§ 102.5 U.S. Veterinary Biological Product License.

(a) Authorization to produce each biological product shall be specified on a U.S. Veterinary Biological Product License, issued by the Administrator, and supplementary to the U.S. Veterinary Biologics Establishment License named therein.

(b) The following shall appear on the U.S. Veterinary Biological Product License:

(1) The U.S. Veterinary Biologics Establishment License Number for the establishment from which the product is released for marketing.

(2) The true name of the product.

(3) The product code number for the product.

(4) The date of issuance.

(5) Any restrictions designated by the Administrator under paragraph (e) of this section.

(6) When necessary to comply with § 102.6 of this part, a termination date and a brief description of requirements to be met for reissuance.

(c) The following provisions shall apply to all licensed biological products:

(1) Licensed biological products shall be prepared as required by the regulations and in accordance with a filed Outline of Production as prescribed in §§ 114.8 and 114.9 of this subchapter. No change shall be made in the preparation of a biological product without prior approval of the Administrator.

(2) In addition to restrictions imposed by the Administrator pursuant to paragraph (e) of this section, biological products may be subject to restrictions which are imposed by any State or other jurisdiction pertaining to the distribution and use of such products, based on local disease conditions.

(3) When requested by the Administrator, a licensee shall submit a list of licensed biological products prepared in the licensed establishment.

(d) Where the Administrator determines that the protection of domestic animals or the public health, interest, or safety, or both, necessitates restrictions on the use of a product, the product shall be subject to such additional restrictions as are prescribed on the license. Such restrictions may include, but are not limited to, limits on distribution of the product or provisions that the biological product is restricted to use by veterinarians, or under the supervision of veterinarians, or both.

(e) Any person may request that the distribution and use of a veterinary biological product be restricted if the restriction pertains to the protection of domestic animals or the public health, interest, or safety, or both. All requests must be sent, in writing, to the Director, Center for Veterinary Biologics, Policy, Evaluation, and Licensing, 1920 Dayton Avenue, P.O. Box 844, Ames, IA 50010. Requests must specify the restriction(s) being requested and must explain why the restrictions are needed. Copies of any supporting documents, such as scientific literature, published or unpublished articles, or data from tests, should be attached to the request. When a decision is reached regarding the request, the person submitting the request will be sent written notification of such decision.

(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; 50 FR 50764, Dec. 12, 1985; 52 FR 11026, Apr. 7, 1987; 56 FR 66783, Dec. 26, 1991; 57 FR 38760, Aug. 27, 1992; 59 FR 67616, Dec. 30, 1994; 62 FR 13294, Mar. 20, 1997; 64 FR 43044, Aug. 9, 1999; 75 FR 20772, Apr. 21, 2010]

§ 102.6 Conditional licenses.

In order to meet an emergency condition, limited market, local situation, or other special circumstance, including production solely for intrastate use under a State-operated program, the Administrator may, in response to an application submitted as specified in