

SUBCHAPTER E—VIRUSES, SERUMS, TOXINS, AND ANALOGOUS PRODUCTS; ORGANISMS AND VECTORS

PART 101—DEFINITIONS

Sec.

- 101.1 Applicability.
- 101.2 Administrative terminology.
- 101.3 Biological products and related terms.
- 101.4 Labeling terminology.
- 101.5 Testing terminology.
- 101.6 Cell cultures.
- 101.7 Seed organisms.

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

SOURCE: 38 FR 8426, Apr. 2, 1973, unless otherwise noted.

§ 101.1 Applicability.

When used in parts 101 through 117 of this subchapter, the meaning of the words and phrases listed shall be as defined in this part.

§ 101.2 Administrative terminology.

The following administrative words and phrases shall mean:

Adjacent herd. Adjacent herds are herds physically contiguous to the herd of origin; there are no herds between an adjacent herd and the herd of origin.

Administrator. The Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the Administrator.

Animal and Plant Health Inspection Service. The agency in the Department of Agriculture responsible for administering the Virus-Serum-Toxin Act.

Biological products. The term *biological products*, also referred to in this subchapter as biologics, biologicals, or products, shall mean all viruses, serums, toxins (excluding substances that are selectively toxic to microorganisms, e.g., antibiotics), or analogous products at any stage of production, shipment, distribution, or sale, which are intended for use in the treatment of animals and which act primarily through the direct stimulation, supplementation, enhancement, or modulation of the immune system or immune response. The term "biological products" includes but is not limited to vaccines, bacterins, allergens, antibodies, antitoxins, toxoids,

immunostimulants, certain cytokines, antigenic or immunizing components of live organisms, and diagnostic components, that are of natural or synthetic origin, or that are derived from synthesizing or altering various substances or components of substances such as microorganisms, genes or genetic sequences, carbohydrates, proteins, antigens, allergens, or antibodies.

(1) A product's intended use shall be determined through an objective standard and not a subjective one, and would be dependent on factors such as representations, claims (either oral or written), packaging, labeling, or appearance.

(2) The term *analogous products* shall include:

(i) Substances, at any stage of production, shipment, distribution, or sale, which are intended for use in the treatment of animals and which are similar in function to biological products in that they act, or are intended to act, through the stimulation, supplementation, enhancement, or modulation of the immune system or immune response; or

(ii) Substances, at any stage of production, shipment, distribution, or sale, which are intended for use in the treatment of animals through the detection or measurement of antigens, antibodies, nucleic acids, or immunity; or

(iii) Substances, at any stage of production, shipment, distribution, or sale, which resemble or are represented as biological products intended for use in the treatment of animals through appearance, packaging, labeling, claims (either oral or written), representations, or through any other means.

(3) The term *treatment* shall mean the prevention, diagnosis, management, or cure of diseases of animals.

Department. The U.S. Department of Agriculture.

Distributor. A person who sells, distributes, or otherwise places in channels of trade, one or more biological

products he does not produce or import.

Division. A marketing unit established by the licensee which may be named on labels, advertisements and promotional material in addition to the name and address of the producer.

Domestic animals. All animals, other than man, including poultry.

Establishment. One or more premises designated on the establishment license.

Guidelines. Guidelines establish principles or practices related to test procedures, manufacturing practices, product standards, scientific protocols, labeling, and other technical or policy considerations. Guidelines contain procedures or standards of general applicability that are usually not regulatory in nature, but that are related to matters that fall under the Virus-Serum-Toxin Act. Guidelines issued by the agency include Veterinary Biologics Licensing Considerations, Memoranda, Notices, and Supplemental Assay Methods.

Herd. Any group of animals, including birds, fish, and reptiles, maintained at a common location (e.g. lot, farm or ranch) for any purpose. The herd (or flock) includes all animals subsequently housed at the common location. If the principal animals of a group are moved to a different location, the group is still considered the same herd.

Herd of origin. The herd from which the microorganism used as seed for production of an autogenous biologic is isolated. Offspring and excess breeding stock (not the principal animals) moved or sold from one group of animals to another have changed herds and are no longer considered part of the herd they originated from. Groups of animals under the same ownership but at different locations are separate herds.

Inspection. An examination made by an inspector to determine the fitness of animals, establishments, facilities, and procedures used in connection with the preparation, testing, and distribution of biological products and the examination or testing of biological products.

Inspector. Any officer or employee of Animal and Plant Health Inspection Service who is authorized by the Administrator to do inspection work.

Licensed establishment. An establishment operated by a person holding an unexpired, unsuspended, and unrevoked U.S. Veterinary Biologics Establishment License.

Licensee. A person to whom an establishment license and at least one product license has been issued.

Microorganisms. Microscopic or sub-microscopic organisms, which are sometimes referred to as organisms, which may introduce or disseminate disease of animals.

Nonadjacent herd. Nonadjacent herds are all herds other than the herd of origin and other than herds adjacent to the herd of origin. Herds adjacent to the herd of origin but in a different State from the herd of origin are also considered nonadjacent herds.

Permittee. A person who resides in the United States or operates a business establishment within the United States, to whom a permit to import biological products has been issued.

Person. Any individual, firm, partnership, corporation, company, association, educational institution, State or local governmental agency, or other organized group of any of the foregoing, or any agent, officer, or employee of any thereof.

Premises. All buildings, appurtenances, and equipment used to produce and store biological products located within a particular land area shown on building plans or drawings furnished by the applicant or the licensee and designated by an address adequate for identification.

Prepare or preparation. Sometimes referred to as manufacture or produce, means the steps and procedures used in the processing, testing, packaging, labeling, and storing of a biological product.

Regulations. The provisions in parts 101 through 118 of this subchapter.

Research investigator or research sponsor. A person who has requested authorization to ship an experimental biological product for the purpose of evaluating such product, or has been granted such authorization.

Secretary. The Secretary of Agriculture of the United States or any officer or employee of the Department to whom authority has heretofore been delegated, or to whom authority may

hereafter be delegated, to act in his stead.

Subsidiary. A corporation in which a corporate licensee owns in excess of 50 percent of the voting stock.

Veterinary Services. Veterinary Services unit of Animal and Plant Health Inspection Service of the Department.

Virus-Serum-Toxin Act. The Act of March 4, 1913, 37 Stat. 832-833; as amended December 23, 1985, Public Law 99-198, 99 Stat. 1654-1655; and as further amended September 28, 1988, Public Law 100-449, 102 Stat. 1868; 21 U.S.C. 151-159.

U.S. Veterinary Biological Product License. A document, sometimes referred to as a product license, which is issued pursuant to part 102 of this subchapter to the holder of an establishment license, as a part of and ancillary to the establishment license, and which authorizes production of a specified biological product in the designated licensed establishment.

U.S. Veterinary Biological Product Permit. A document, sometimes referred to as a permit, issued to a person authorizing the importation of specified biological products subject to restrictions and controls as provided in the regulations.

U.S. Veterinary Biologics Establishment License. A document referred to as an establishment license, which is issued pursuant to part 102 of this subchapter, authorizing the use of designated premises for production of biological products specified in one or more unexpired, unsuspended, and unrevoked product license(s).

[38 FR 8426, Apr. 2, 1973; 38 FR 9221, Apr. 12, 1973, as amended at 40 FR 46093, Oct. 6, 1975; 41 FR 44358, Oct. 8, 1976; 49 FR 22624, May 31, 1984; 52 FR 30131, Aug. 13, 1987; 56 FR 66782, 66783, Dec. 26, 1991; 57 FR 38756, Aug. 27, 1992; 62 FR 31328, June 9, 1997; 64 FR 43044, Aug. 9, 1999]

§ 101.3 Biological products and related terms.

When used in conjunction with or in reference to a biological product, the following terms shall mean:

(a) *Licensed biological product.* A biological product prepared within a licensed establishment by a person holding an unexpired, unsuspended, and

unrevoked product license for such product.

(b) *Experimental biological product.* A biological product which is being evaluated to substantiate an application for a product license or permit.

(c) *Completed product.* A biological product in bulk or final container produced in compliance with the regulations to final form and composition.

(d) *Finished product.* A completed product which has been bottled, sealed, packaged, and labeled as required by the regulations.

(e) *Released product.* A finished product released for marketing after all requirements have been satisfactorily complied with.

(f) *Fraction.* A specific antigen, its antibodies, or its antitoxin which constitutes a component of a biological product.

(g) *Diluent.* A liquid used to rehydrate a desiccated product or a liquid used to dilute another substance.

(h) *Serial.* The total quantity of completed product which has been thoroughly mixed in a single container and identified by a serial number: *Provided*, That, when all or part of a serial of liquid biological product is packaged as diluent for all or part of a serial of desiccated product, the resulting combination packages shall be considered a serial of the multiple fraction product.

(i) *Subserial.* Each of two or more properly identified portions of a serial which are further processed at different times or under different conditions such as, but not limited to, being desiccated in different size final containers and/or at different times.

(j) *Outline of production.* A detailed protocol of methods of manufacture to be followed in the preparation of a biological product and which may sometimes be referred to as an outline.

(k) *Product Code Number.* A number assigned by Animal and Plant Health Inspection Service to each type of licensed biological product.

(l) *Harvest date.* Unless otherwise specified in a filed Outline of Production, the harvest date shall be the date blood or tissues are collected for production or the date cultures of living microorganisms are removed from production incubators.