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.

(m) *Bacterin.* An inactivated bacterial product consisting of an antigenic suspension of organisms or particulate parts of organisms, representing a whole culture or a concentrate thereof, with or without the unevaluated growth products, which has been inactivated as demonstrated by acceptable tests written into the filed Outline of Production for the product.

(n) *Toxoid.* An inactivated bacterial product which consists of a sterile, antigenic toxin or toxic growth product, which has resulted from the growth of bacterial organisms in a culture medium from which the bacterial cells have been removed, which has been inactivated without appreciable loss of antigenicity as measured by suitable tests, and which is nontoxic as demonstrated by acceptable tests written into the filed Outline of Production.

(o) *Bacterin-toxoid.* An inactivated bacterial product which is either:

(1) A suspension of organisms, representing a whole culture or a concentrate thereof, with the toxic growth products from the culture which has been inactivated without appreciable loss of antigenicity as measured by suitable tests, the inactivation of organisms and toxins being demonstrated by acceptable tests written into the filed Outline of Production: *Provided,* That it shall contain cellular antigens and shall stimulate the development of antitoxin; or

(2) A combination product in which one or more toxoids or bacterin-toxoids is combined with one or more bacterins or one or more bacterin-toxoids.

(p) *Bacterial extract.* An inactivated bacterial product which consists of the sterile, nontoxic, antigenic derivatives extracted from bacterial organisms or from culture medium in which bacterial organisms have grown.

[38 FR 8426, Apr. 2, 1973, as amended at 42 FR 63770, Dec. 20, 1977; 50 FR 24903, June 14, 1985; 56 FR 66782, Dec. 26, 1991; 60 FR 14354, Mar. 17, 1995]

§ 101.4 Labeling terminology.

Terms pertaining to identification and packaging of biological products shall mean:

(a) *Label.* All written, graphic, or printed matter:

(1) Upon or attached to a final container of a biological product;

(2) Appearing upon any immediate carton or box used to package such final container; and

(3) Appearing on any accompanying enclosures (leaflets, inserts, or circulars) on which required information or directions as to the use of the biological product shall be found.

(b) *Labeling.* All labels and other written, printed, or graphic matter accompanying the final container.

(c) *Final container.* The unit, bottle, vial, ampule, tube, or other receptacle into which any biological product is filled for distribution and sale.

(d) *True name.* The name entered on the product license or permit at the time of issuance to differentiate the biological product from others: *Provided,* That, the principal part of such name shall be emphasized on such license or permit by being more prominently lettered than descriptive terms which may be necessary to complete the differentiation.

(e) *Serial number.* Numbers or numbers and letters used to identify and distinguish one serial from others.

(f) *Expiration date.* A date designating the end of the period during which a biological product, when properly stored and handled, can be expected with reasonable certainty, to be efficacious.

(g) *Label number.* A number assigned by Animal and Plant Health Inspection Service to each label or sketch submitted for review.

(h) *Master label.* The finished carton, container, or enclosure label for the smallest size final container that is authorized for a biological product, that serves as the Master template label applicable to all other size containers or cartons of the same product that is marketed by a licensee, subsidiary, division, or distributor.

[38 FR 8426, Apr. 2, 1973, as amended at 42 FR 63770, Dec. 20, 1977; 56 FR 66782, Dec. 26, 1991; 61 FR 29464, June 11, 1996]

§ 101.5 Testing terminology.

Terms used when evaluating biological products shall mean: