

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:

(a) *Standard Requirement*. Test methods, procedures, and criteria established by Animal and Plant Health Inspection Service for evaluating biological products to be pure, safe, potent, and efficacious, and not to be worthless, contaminated, dangerous, or harmful under the Act.

(b) *Log*. Logarithm computed to the base 10.

(c) *Pure or purity*. Quality of a biological product prepared to a final form relatively free of extraneous microorganisms and extraneous material (organic or inorganic) as determined by test methods or procedures established by Animal and Plant Health Inspection Service in Standard Requirements or in the approved Outline of Production for such product, but free of extraneous microorganisms or material which in the opinion of the Administrator ad-

versely affects the safety, potency, or efficacy of such product.

(d) *Safe or safety*. Freedom from properties causing undue local or systemic reactions when used as recommended or suggested by the manufacturer.

(e) *Sterile or sterility*. Freedom from viable contaminating microorganisms as demonstrated by procedures prescribed in part 113 of this subchapter, Standard Requirements, and approved Outlines of Production.

(f) *Potent or potency*. Relative strength of a biological product as determined by test methods or procedures as established by Animal and Plant Health Inspection Service in Standard Requirements or in the approved Outline of Production for such product.

(g) *Efficacious or efficacy*. Specific ability or capacity of the biological product to effect the result for which it is offered when used under the conditions recommended by the manufacturer.

(h) *Dose*. The amount of a biological product recommended on the label to be given to one animal at one time.

(i) *Vaccinate*. An animal which has been inoculated, injected, or otherwise administered a biological product being evaluated.

(j) *Control animal*. An animal, which may be referred to as a control, used in a test procedure for purposes of comparison or to add validity to the results.

(k) *Day*. Time elapsing between any regular working hour of one day and any regular working hour of the following day.

(l) *No test*. A test which produces inconclusive or invalid results and therefore, cannot be used to evaluate a biological product.

(m) *Healthy*. Apparently normal in all vital functions and free of signs of disease.

(n) *Unfavorable reactions*. Overt adverse changes which occur in healthy test animals subsequent to initiation of a test and manifested during the observation period prescribed in the test protocol which are attributable either to the biological product being tested or to factors unrelated to such product

as determined by the responsible individual conducting the test.

[38 FR 8426, Apr. 2, 1973, as amended at 40 FR 45419, Oct. 2, 1975; 41 FR 6751, Feb. 13, 1976; 43 FR 3701, Jan. 27, 1978; 56 FR 66782, 66783 Dec. 26, 1991]

§ 101.6 Cell cultures.

When used in conjunction with or in reference to cell cultures, which may be referred to as tissue cultures, the following terms shall mean:

(a) *Batches of primary cells*. A pool of original cells derived from normal tissue up to and including the 10th subculture.

(b) *Cell line*. A pool of cells which are 11 or more subcultures from the tissue of origin.

(c) *Subculture*. Each flask to flask transfer or passage regardless of the number of cell replications.

(d) *Master Cell Stock (MCS)*. The supply of cells of a specific passage level from which cells for production of biologics originate.

[38 FR 8426, Apr. 2, 1973, as amended at 40 FR 45419, Oct. 2, 1975; 49 FR 22624, May 31, 1984]

§ 101.7 Seed organisms.

When used in conjunction with or in reference to seed organisms, the following shall mean:

(a) *Master Seed*. An organism at a specific passage level which has been selected and permanently stored by the producer from which all other seed passages are derived within permitted levels.

(b) *Working Seed*. An organism at a passage level between Master Seed and Production Seed.

(c) *Production Seed*. An organism at a specified passage level which is used without further propagation for initiating preparation of a fraction.

[49 FR 22625, May 31, 1984]

PART 102—LICENSES FOR BIOLOGICAL PRODUCTS

Sec.

102.1 Licenses issued by the Administrator.

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102.6 Conditional licenses.

AUTHORITY: 21 U.S.C. 151-159; 7 CFR 2.22, 2.80, and 371.2(d).

§ 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 furnished 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.