

§ 113.4

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a licensed product shall be submitted only upon request from the animal and Plant Health Inspection Service. Except for miscellaneous products specified in paragraph (b)(9) of this section, the number of such samples shall be at least one and one-half times the number prescribed for such product in paragraph (b) of this section. Samples of Master Seeds and Master Cell Stocks with a minimum individual volume of 1 ml shall be submitted as follows:

(1) Ten samples of Bacterial Master Seeds.

(2) Thirteen samples of viral Master Seeds or nonviral Master Seeds requiring cell culture propagation. For Master Seeds isolated or passed in a cell line different from the species of intended use, an additional 2 samples are required for each additional species. For Master Seeds grown in cell culture and intended for use in more than one species, an additional 2 samples are required for each additional species.

(3) Thirty-six samples of at least 1 ml each or six samples of at least 1 ml each, one sample of at least 20 ml, and one sample of at least 10 ml of Master Cell Stocks which are persistently infected with a virus, an additional four samples of at least 1 ml each are required. If these persistently infected cell stocks are intended for use in more than one species, an additional two samples of at least 1 ml each are required for each additional species.

(4) Four samples of the Master Cell Stock + n (highest passage) cells.

(d) Sterile diluent: A sample of Sterile Diluent shall accompany each sample of product, other than Marek's Disease Vaccine, if such diluent is required to rehydrate or dilute the product before use. The volume of diluent shall be an appropriate amount to rehydrate or dilute the product. Samples of Sterile Diluent prepared for use with Marek's Disease Vaccine shall be submitted upon request from the Animal and Plant Health Inspection Service.

(e) Reserve samples shall be selected from each serial and subserial of biological product. Such samples shall be selected at random from final containers of completed product by an employee of the Department, of the licensee, or of the permittee, as des-

ignated by the administrator. Each sample shall:

(1) Consist of 5 single-dose packages, 2 multiple-dose packages, or 2 diagnostic test kits, except that, in the case of diagnostic test kits in which final packaging consists of multiple microtiter test plates or strips, a sample may consist of a specified number of test plates or strips along with all other test reagents as prescribed in a filed Outline of Production;

(2) Be adequate in quantity for appropriate examination and testing;

(3) Be truly representative and in final containers;

(4) Be held in a special compartment set aside by the licensee or permittee for holding these samples under refrigeration at the storage temperature recommended on the labels for 6 months after the expiration date stated on the labels. The samples that are stored in this manner shall be delivered to the Animal and Plant Health Inspection Service upon request.

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

[38 FR 29886, Oct. 30, 1973, as amended at 40 FR 758, Jan. 3, 1975; 40 FR 49768, Oct. 24, 1975; 41 FR 56627, Dec. 29, 1976; 48 FR 9506, Mar. 7, 1983; 48 FR 57473, Dec. 30, 1983; 50 FR 21799, May 29, 1985; 56 FR 66784, Dec. 26, 1991; 60 FR 14356, Mar. 17, 1995]

§ 113.4 Exemptions to tests.

(a) The test methods and procedures contained in all applicable Standard Requirements shall be complied with unless otherwise exempted by the Administrator and provided that such exemption is noted in the filed Outline of Production for the product.

(b) Test methods and procedures by which the biological products shall be evaluated shall be designated in the Outline of Production for such products.

[38 FR 29887, Oct. 30, 1973, as amended at 56 FR 66784, Dec. 26, 1991]

§ 113.5 General testing.

(a) No biological product shall be released prior to the completion of tests prescribed in a filed Outline of Production or Standard Requirements for the product to establish the product to be pure, safe, potent, and efficacious.