

§ 114.3

(4) Reports prescribed in § 116.5 of this subchapter for USDA-licensed establishments shall be submitted for all veterinary biological products in the establishment.

(5) Under the following conditions, an autogenous biologic may be produced in a USDA-licensed establishment under either a State or U.S. Veterinary Biological Product License:

(i) When a culture of microorganisms, isolated from a herd in a State, is received at a USDA-licensed establishment that is in the same State but that holds both a State and a U.S. Veterinary Biological Products License for autogenous biologics, the isolate shall be designated by the licensee for use in the production of an autogenous biological product under either the State product license, or the U.S. Veterinary Biological Product License: *Provided*, That the isolate meets the requirements of the respective regulatory authority for an autogenous biologic. If, after producing the product pursuant to one license, the licensee elects to produce an autogenous biologic from the same isolate under provisions of the other license, the licensee may do so only with the approval of the other licensing authority.

(ii) The true name of a State-licensed autogenous biologic shall specify the State of licensure: e.g.

“ _____ Autogenous Bacterin”

(State)

or _____ Autogenous Vaccine”.

(State)

[39 FR 16869, May 10, 1974, as amended at 60 FR 48021, Sept. 21, 1995]

§ 114.3 Separation of establishments.

(a) Each licensed establishment shall be separate and distinct from any other establishment in which a biological product is prepared.

(b) No biological products authorized to be prepared in a licensed establishment shall be prepared in whole or in part by another licensed establishment except as provided in paragraphs (c) and (d) of this section.

(c) When a partially prepared biological product cannot be completed at a licensed establishment due to failure of essential equipment, the Administrator may authorize the use of similar equip-

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ment at another licensed establishment: *Provided*, That, such authorization shall be limited to the duration of the emergency and to the phase of production affected by the equipment failure.

(d) Partially prepared products or serials of completed products for further manufacture may be moved from one licensed establishment to another licensed establishment, imported under the provisions of § 104.5, or moved from a licensed establishment for purpose of being exported under conditions prescribed in an Outline of Production filed with Animal and Plant Health Inspection Service. Licensed products or products imported for distribution and sale may be prepared and recommended for final use, for further manufacturing purposes, or both. All serials shall be subject to the requirements for testing and release specified in § 113.5 or § 113.10 and to the requirements for identification specified in § 114.4.

[39 FR 16869, May 10, 1974, as amended at 40 FR 46093, Oct. 6, 1975; 49 FR 45846, Nov. 21, 1984; 56 FR 66784, Dec. 26, 1991]

§ 114.4 Identification of biological products.

Suitable tags or labels of a distinct design shall be used for identifying all ingredients used in the preparation of biological products, all component parts to be combined to form a biological product, all biological products while in the course of preparation and all completed biological products held in storage at licensed establishments: *Provided*, That, if such ingredients, components, or biological products are not so identified, they shall be disposed of as provided in § 114.15.

§ 114.5 Micro-organisms used as seed.

Micro-organisms used in the preparation of biological products at licensed establishments shall be free from the causative agents of other diseases or conditions. A complete record of such micro-organisms shall be kept currently correct and a list submitted to Animal and Plant Health Inspection