

U.S. Customs and Border Protection, DHS; Treasury

§ 12.23

§ 12.20 Disposition.

Viruses, serums, or toxins rejected by the Department of Agriculture shall be released by the port director to that Department for destruction, or exported under Customs supervision at the expense of the importer if exportation is authorized by the Department of Agriculture.

VIRUSES, SERUMS, TOXINS, ANTITOXINS,
AND ANALOGOUS PRODUCTS FOR THE
TREATMENT OF MAN

§ 12.21 Licensed establishments.

The bringing into the United States for sale, barter, or exchange, of any virus, therapeutic serum, toxin, antitoxin, or analogous product, or arsphenamine or its derivatives (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of diseases or injuries of man is prohibited unless such virus, serum, toxin, antitoxin, or other product has been manufactured at an establishment holding an unsuspended and unrevoked license issued by the Secretary of Health and Human Services for such manufacture.

[T.D. 69-201, 34 FR 14328, Sept. 12, 1969, as amended by T.D. 82-145, 47 FR 35476, Aug. 16, 1982]

§ 12.22 Labels; samples.

Each package of such products imported for sale, barter, or exchange shall be labeled or plainly marked with the name, address, and license number of the manufacturer, and the date beyond which the contents cannot be expected to yield their specific results. From each lot of product the port director shall select at random at least two final containers. The random sample together with a copy of the associated documents which describe and identify the shipment shall be forwarded to the Director, Bureau of Biologics, Food and Drug Administration, 8800 Rockville Pike, Bethesda, Md. 20014. For shipments of 20 or less final containers, samples need not be forwarded, provided a copy of an official

release from the Bureau of Biologics accompanies each shipment.

[T.D. 69-201, 34 FR 14328, Sept. 12, 1969, as amended by T.D. 82-145, 47 FR 35476, Aug. 16, 1982]

§ 12.23 Detention; examination; disposition.

(a) Port directors shall detain all importations of unlicensed viruses, therapeutic serums, toxins, antitoxins, and analogous products, and arsphenamines or its derivatives (or any other trivalent organic arsenic compound) for the treatment or cure of diseases or injuries of man pending examination by the Director, Bureau of Biologics, unless satisfied from evidence furnished at the time of entry that the products are intended solely for purposes of controlled investigation and not for sale, barter, or exchange, as evidenced by a copy of a filed "Notice of Claimed Investigational Exemption for a New Drug," pursuant to §312.1 of the Food, Drug, and Cosmetic Act Regulations (21 CFR 312.1), or are being imported under the short supply provisions of §601.22 of the Public Health Service Regulations (42 CFR 601.22).

(b) If the shipment is imported for sale, barter, or exchange and is found by the Director, Division of Biologics Standards, to be admissible, the port director shall release it upon receipt of a report from him that the shipment is admissible.

(c) If the Director, Division of Biologics Standards, reports that the shipment was found upon examination not to conform to the law and the regulations, the port director shall not release the shipment but shall permit the exportation or destruction thereof under Customs supervision at the option of the importer.

(d) Shipments of such products for use in the treatment of man but made from or with material of animal origin other than human, shall, unless accompanied by a Department of Agriculture, Veterinary Services, Animal and Plant Health Inspection Service (APHIS) permit, be detained until proof is presented to the port director that their