

information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at <http://www.aphis.usda.gov/ppd/rad/webrepor.html>.

**FOR FURTHER INFORMATION CONTACT:** Dr. Albert P. Morgan, Chief of Operational Support, Center for Veterinary Biologics, Licensing and Policy Development, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1231, (301) 734–8245.

**SUPPLEMENTARY INFORMATION:**

**Background**

Parts 105 and 115 of the Virus-Serum-Toxin Act regulations (9 CFR parts 105 and 115, referred to below as the regulations) provide, respectively, for the suspension, revocation, or termination of biological licenses or permits and for the inspection of veterinary biologics establishments and veterinary biological products. These regulations also contain provisions that address the actions to be taken by veterinary biologics licensees, permittees, jobbers, wholesalers, dealers, or other persons known to have veterinary biologics in their possession, upon their receipt of notice from the Animal and Plant Health Inspection Service (APHIS) to stop the preparation, distribution, sale, barter, exchange, shipment, or importation of worthless, contaminated, dangerous, harmful, or unsatisfactory veterinary biological product.

Section 105.3 of the regulations provides, in relevant part, that APHIS may notify a licensee or permittee to stop the preparation, sale, barter, exchange, shipment, or importation of any veterinary biological product if at any time it appears that such product may be dangerous in the treatment of domestic animals, or found to be unsatisfactory according to applicable Standard Requirements.

Similarly, § 115.2 provides, in relevant part, that if as a result of any inspection it appears that any veterinary biological product is worthless, contaminated, dangerous, or harmful, the Secretary will give notice of that finding to the manufacturer or importer and to any jobbers, wholesalers, dealers or other persons known to have any of such product in their possession. After receiving such notice, no person may sell, barter, or exchange any such product in any place under the jurisdiction of the United States or ship or deliver for shipment any such product in or from any State, Territory, or the District of Columbia.

Typically, before the stop distribution and sale notifications provided for by §§ 105.3 and 115.2 can be given, APHIS must obtain from the licensees and permittees (manufacturers or importers) the names and addresses of the wholesalers, dealers, jobbers, consignees, or other persons known to have any of the product in their possession. Any delay in obtaining the names and addresses of persons in possession of biological products subject to a stop distribution and sale action increases the risk that such product may cause harm to animals, the public health, or to the environment. APHIS believes that it is prudent to use the most expeditious means available to notify wholesalers, dealers, jobbers, consignees, or other persons concerning the stop distribution and sale action. Therefore, this proposed rule would amend §§ 105.3 and 115.2 to specify actions that veterinary biologics licensees and permittees would have to take when APHIS issues a stop distribution and sale notice concerning a veterinary biological product.

Specifically, APHIS is proposing to amend the regulations to provide that APHIS would contact veterinary biologics licensees and permittees concerning stop distribution and sale actions against any worthless, contaminated, dangerous, harmful, or unsatisfactory veterinary biological product. After being contacted by APHIS, veterinary biologics licensees or permittees would be required to immediately provide stop distribution and sale notification to wholesalers, jobbers, dealers, consignees or other persons in their respective distribution systems known to be in possession of such product. APHIS believes that having licensees or permittees provide stop distribution and sale notification to wholesalers, jobbers, dealers, consignees, or other persons in their respective distribution systems known to be in possession of any worthless, contaminated, dangerous, harmful, or unsatisfactory veterinary biological product is the most expeditious means of notification. Licensees and permittees have information readily available to them concerning the products that have been shipped to wholesalers, jobbers, dealers, consignees, or other persons in their respective distribution systems.

In addition, veterinary biologics licensees and permittees also would be required to document, in writing, all communications with wholesalers, dealers, jobbers, consignees, or other persons concerning the stop distribution and sale action; obtain a complete accounting of the inventory of such product in the possession of such

wholesalers, jobbers, dealers, and other persons; and, as directed by the Administrator, submit records of all actions taken to ensure compliance with the stop distribution and sale notification.

**Executive Order 12866 and Regulatory Flexibility Act**

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for purposes of Executive Order 12866, and, therefore, has not been reviewed by the Office of Management and Budget.

APHIS issues stop distribution and sale actions if information is received indicating that a serial or subserial of a licensed veterinary biological product is worthless, contaminated, dangerous, harmful, or unsatisfactory. Such information may come from inspection findings, an investigation, an adverse event report, or tests conducted by the Center for Veterinary Biologics Laboratory or by the licensee or permittee. Stop distribution and sale actions may be necessary to prevent risk to the health of animals, to the public health or well-being, or to the environment. Currently, the regulations in §§ 105.3 and 115.2 provide that APHIS may issue a notice requiring veterinary biologics licensees and permittees to stop distribution and sale if a product is found to be unsatisfactory according to applicable standard requirements or if it appears that such product is worthless, contaminated, dangerous, or harmful.

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