

concerning which wholesalers, jobbers, dealers, consignees, or other persons in their respective distribution systems are known to be in possession of products.

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.

The effect of this action would be to clarify the regulations, provide for the most expeditious means of notification, and to prevent the risk that any worthless, contaminated, dangerous, harmful, or unsatisfactory veterinary biological product may cause harm to animals, the public health, or to the environment.

This proposed rule would affect all veterinary biologics licensees and permittees. Currently, there are approximately 135 veterinary biological establishments, including permittees. According to the standards of the Small Business Administration, most veterinary biological establishments would be classified as small entities.

Section 116.2 of the regulations currently requires licensees and permittees to maintain records of the quantity and location of each biological product that is prepared, that is in storage, and that is in distribution channels. In addition, each licensee, distributor, and permittee must maintain detailed disposition records showing the sale, shipment, or other disposition of any biological products that they have handled. Given these existing recordkeeping requirements, APHIS believes that the proposed requirement that licensees and permittees submit to APHIS a complete accounting of the inventory of an affected serial or subserial of a biological product in the current possession of each person involved in the distribution or sale of the product should not impose any undue recordkeeping burden. APHIS also believes that the current requirement for the maintenance of detailed disposition records would enable licensees and permittees to notify persons in their distribution system concerning stop distribution and sale notifications issued by APHIS without having to incur any undue recordkeeping burden.

APHIS anticipates that the only economic effects that would be associated with this proposed rule would be related to the costs incurred by licensees and permittees in connection with the notification process itself. This proposed rule does not specify the means by which licensees and permittees are required to give notification, only that the notification be made by them immediately upon receipt of the stop distribution and sale notification from APHIS. APHIS expects that most licensees and permittees would use electronic mail or facsimile to notify wholesalers, jobbers, dealers, consignees, or other persons in their respective distribution systems known to be in possession of any biological product for which APHIS has issued a stop distribution and sale action. Both of these methods are inexpensive, so the actual transmittal costs associated with the proposed notification requirement would be minimal.

Licensees and permittees could retain electronic mail return receipts or facsimile confirmation sheets to address the proposed requirement for documentation that notifications have been made, both of which can be produced automatically by the sender's electronic mail system or facsimile machine. There would be some personnel costs associated with producing and addressing the notification document that would have to be sent out, but the existing requirement for the maintenance of detailed disposition records discussed in the previous paragraph should serve to minimize, to the extent possible, the time spent engaging in those activities.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

#### **Executive Order 12372**

This program is listed in the category of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.).

#### **Executive Order 12988**

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. This rule would not preempt any State or local laws, regulations, or policies unless they present an irreconcilable conflict with this rule. The Virus-Serum-Toxin Act does not provide administrative

procedures which must be exhausted prior to a judicial challenge to the provisions of this rule.

#### **Paperwork Reduction Act**

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. 02-107-1. Please send a copy of your comments to: (1) Docket No. 02-107-1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737-1238, and (2) Clearance Officer, OCIO, USDA, room 404-W, 14th Street and Independence Avenue, SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

In this document, we are proposing to amend the regulations in §§ 105.3 and 115.2 to specify actions that veterinary biologics licensees and or permittees would have to take when APHIS issues a stop distribution and sale notice concerning a veterinary biological product. This process would entail the use of two new information collection activities.

First, 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.

Second, veterinary biologics licensees and permittees would have to obtain a complete accounting of the inventory of such product in the possession of such wholesalers, jobbers, dealers, and other persons in their distribution system.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

- (1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;
- (2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the