

validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; e.g., permitting electronic submission of responses).

Estimate of burden: Public reporting burden for this collection of information is estimated to average 1.7666 hours per response.

Respondents: Licensees and permittees and wholesalers, dealers, jobbers, consignees, or other persons in their distribution system.

Estimated annual number of respondents: 55.

Estimated annual number of responses per respondent: 1.0909.

Estimated annual number of responses: 60.

Estimated total annual burden on respondents: 106 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

Copies of this information collection can be obtained from Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734-7477.

Government Paperwork Elimination Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the Government Paperwork Elimination Act (GPEA), which requires government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible. For information pertinent to GPEA compliance related to this proposed rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734-7477.

List of Subjects

9 CFR Part 105

Animal biologics, Exports, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

9 CFR Part 115

Animal biologics, Exports, Imports, Reporting and recordkeeping requirements.

Accordingly, we propose to amend 9 CFR parts 105 and 115 as follows:

PART 105—SUSPENSION, REVOCATION, OR TERMINATION OF BIOLOGICAL LICENSES OR PERMITS

1. The authority citation for part 105 would continue to read as follows:

Authority: 21 U.S.C. 151-159; 7 CFR 2.22, 2.80, and 371.4.

2. Section 105.3 would be amended by adding a new paragraph (c) to read as set forth below:

105.3 Notices re: worthless, contaminated, dangerous, or harmful biological products.

* * * * *

(c) When notified to stop distribution and sale of a serial or subserial of a veterinary biological product under the provisions of paragraph (a) or (b) of this section, veterinary biologics licensees or permittees shall:

(1) Stop the preparation, distribution, sale, barter, exchange, shipment, or importation of the affected serial(s) or subserial(s) of any veterinary biological product pending further instructions from APHIS.

(2) Immediately send stop distribution and sale notifications to any jobbers, wholesalers, dealers, foreign consignees, or other persons known to have any such veterinary biological product in their possession, which instruct them to stop the preparation, distribution, sale, barter, exchange, shipment, or importation of any such veterinary biological product. All notifications shall be documented in writing by the licensee or permittee.

(3) Account for the quantity of each serial(s) or subserial(s) of any veterinary biological product at each location in the distribution channel.

(4) When required by the Administrator, submit complete and accurate reports of all notifications concerning stop distribution and sale actions to the Animal and Plant Health Inspection Service pursuant to § 116.5 of this subchapter.

PART 115—INSPECTIONS

3. The authority citation for part 115 would continue to read as follows:

Authority: 21 U.S.C. 151-159; 7 CFR 2.22, 2.80, and 371.4.

4. Section 115.2 would be revised to read as follows:

§ 115.2 Inspections of biological products.

(a) Any biological product, the container of which bears a United States veterinary license number or a United States veterinary permit number or

other mark required by these regulations, may be inspected at any time or place. If, as a result of such inspection, it appears that any such product is worthless, contaminated, dangerous, or harmful, the Secretary shall give notice to stop distribution and sale to the manufacturer or importer and may proceed against such product pursuant to the provisions of part 118 of this subchapter.

(b) When notified to stop distribution and sale of a serial or subserial of a veterinary biological product by the Secretary, veterinary biologics licensees or permittees shall:

(1) Stop the preparation, distribution, sale, barter, exchange, shipment, or importation of the affected serial(s) or subserial(s) of any veterinary biological product pending further instructions from APHIS.

(2) Immediately send stop distribution and sale notifications to any jobbers, wholesalers, dealers, foreign consignees, or other persons known to have any such veterinary biological product in their possession, which instruct them to stop the preparation, distribution, sale, barter, exchange, shipment, or importation of any such veterinary biological product. All notifications shall be documented in writing by the licensee or permittee.

(3) Account for the quantity of each serial(s) or subserial(s) of any veterinary biological product at each location in the distribution channel.

(4) When required by the Administrator, submit complete and accurate reports of all notifications concerning stop distribution and sale actions to the Animal and Plant Health Inspection Service pursuant to § 116.5 of this subchapter.

(c) Unless and until the Secretary shall otherwise direct, no persons so notified shall thereafter 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. However, failure to receive such notice shall not excuse any person from compliance with the Virus-Serum-Toxin Act.

Done in Washington, DC, this 2nd day of April, 2003.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

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