Section 956.13 of the order defines ''fiscal period'' and provides the authority by which this recommended change is being proposed. This rule is a change to Committee operations which would not impose any new requirements or costs on Walla Walla sweet onion handlers or producers. It could, on the other hand, simplify the business operations within the Walla Walla sweet onion industry by putting the order's fiscal period on the same basis as that of normal business recordkeeping practices.

The Committee discussed the alternative of leaving the fiscal period as it presently exists, but unanimously concluded that this change, as recommended, would improve program administration.

This rule would not impose any additional reporting or recordkeeping requirements on either small or large Walla Walla sweet onion handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sectors. In addition, USDA has not identified any relevant Federal rules that duplicate, overlap or conflict with this rule.

The Committee's meeting was widely publicized throughout the Walla Walla sweet onion industry and all interested persons were invited to attend the meeting and participate in Committee deliberations. Like all Committee meetings, the December 17, 2002, meeting was a public meeting and all entities, both large and small, were able to express their views on this issue. Finally, interested persons are invited to submit information on the regulatory and informational impacts of this action on small businesses.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *http://www.ama.usda.gov/fv/moab.html.* Any questions about the compliance guide should be sent to Jay Guerber at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

A 60-day comment period is provided to allow interested persons to respond to this proposal. All written comments timely received will be considered before a final determination is made on this matter.

List of Subjects in 7 CFR Part 956

Marketing agreements, Onions, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 956 is proposed to be amended as follows:

PART 956—SWEET ONIONS GROWN IN THE WALLA WALLA VALLEY OF SOUTHEAST WASHINGTON AND NORTHEAST OREGON

1. The authority citation for 7 CFR part 956 continues to read as follows:

Authority: 7 U.S.C. 601–674.

2. A new § 956.113 is added to subpart ''Rules and Regulations'' to read as follows:

§ 956.113 Fiscal period.

Pursuant to § 956.13, *fiscal period* shall mean the period beginning January 1 and ending December 31 of each year.

§ 956.142 [Amended]

3. Section 956.142 is amended by removing the words ''of each fiscal period'' in the second sentence.

§ 956.180 [Amended]

4. Section 956.180 is amended by removing the words ''of each fiscal period'' in the introductory text.

Dated: April 3, 2003.

A. J. Yates,

Administrator, Agricultural Marketing Service.

[FR Doc. 03–8648 Filed 4–8–03; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 105 and 115

[Docket No. 02–107–1]

Viruses, Serums, Toxins, and Analogous Products; Suspension, Revocation, or Termination of Biological Licenses or Permits; Inspections

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the Virus-Serum-Toxin Act regulations to specify the actions that would have to be taken by veterinary biologics licensees and permittees 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 any worthless, contaminated, dangerous, harmful, or unsatisfactory veterinary biological product. After receiving notice from APHIS to stop the preparation, distribution, sale, barter, exchange, shipment, or importation of any worthless, contaminated, dangerous, harmful, or unsatisfactory veterinary biological product, licensees and permittees would be required to notify wholesalers, dealers, jobbers, or other persons known to have veterinary biological products in their possession to stop the preparation, distribution, sale, barter, exchange, shipment, or importation of any worthless, contaminated, dangerous, harmful, or unsatisfactory veterinary biological product. In addition, licensees and permittees would be required to submit a complete accounting of the inventory of affected serials or subserials of biological products in the current possession of each person involved in the distribution or sale of the product, and provide written documentation concerning the required notifications as directed by the Administrator of APHIS. These proposed changes are necessary in order 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.

DATES: We will consider all comments that we receive on or before June 9, 2003.

ADDRESSES: You may submit comments by postal mail/commercial delivery or by e-mail. If you use postal mail/commercial delivery, please send four copies of your comment (an original and three copies) to: Docket No. 02–107–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 02–107–1. If you use e-mail, address your comment to *regulations@aphis.usda.gov.* Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and ''Docket No. 02–107–1'' on the subject line.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

APHIS documents published in the **Federal Register**, and related

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.

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 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

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.

[FR Doc. 03–8599 Filed 4–8–03; 8:45 am]

BILLING CODE 3410–34–P