SUPPORTING STATEMENT
VIRUSES, SERUMS, TOXINS, AND ANALOGOUS PRODUCTS; SUSPENSION, REVOCATION, OR TERMINATION OF BIOLOGICAL LICENSES OR PERMITS
OMB CONTROL NUMBER 0579-0318

April 14, 2009

A. Justification

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

The Virus-Serum-Toxin Act (37 Stat. 832-833, 21 U.S.C. 151-159) gives the United States Department of Agriculture (USDA) the authority to promulgate regulations designed to prevent the importation, preparation, sale, or shipment of harmful veterinary biological products. These regulations are contained in Title 9, Code of Federal Regulations, Subchapter E, Parts 102 to 124.

A veterinary biological product is defined as all viruses, serums, toxins, and analogous products of natural or synthetic origin (such as vaccines, antitoxins, or the immunizing components of microorganisms intended for the diagnosis, treatment, or prevention of diseases in domestic animals).

Under APHIS' regulations in section 105.3(a), the Center for Veterinary Biologics, Animal and Plant Health Inspection Service (APHIS), USDA, may notify a licensee or permittee to stop the preparation, sale, barter, exchange, shipment, or importation of any biological product if, at any time, it appears that such product may be dangerous in the treatment of domestic animals.

APHIS believes it is imperative to use the most expeditious means available to notify anyone who may be in possession of such products that a stop distribution and sale action has occurred. Any delay in this notification process increases the risk that these products could cause harm to animals, the public health, or to the environment. This process entails the use of two information collection activities.

First, licensees and permittees must notify their wholesalers, jobbers, dealers, consignees, or other persons in their respective distribution systems that a stop distribution and sale order has been issued by APHIS.

Second, licenses and permittees must obtain a complete accounting of the inventory of the product in the possession of wholesalers, jobbers, dealers, consignees, or other persons in their respective distribution systems.

APHIS is asking the Office of Management and Budget (OMB) to approve for 3 years, the information collection activities associated with this activity. This information is needed in connection with APHIS' efforts to prevent biological products from harming animals, the public health, or the environment.

2. Indicate how, by whom, how frequently, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

Notify Wholesalers (Licensees and Permittees)

After being contacted by APHIS, veterinary biologics licensees or permittees must 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 serials or subserials of veterinary biologics that are involved in the APHIS stop distribution and sale action. This notification must be documented, in writing, and submitted to APHIS as verification that the notification process has been promptly implemented. In addition to notification information, licensees and permittees must document – and submit to APHIS – any other communications they have with wholesalers, jobbers, dealers, consignees, or others concerning the stop distribution and sale action.

Accounting of Inventory (Licensees and Permittees)
Accounting of Inventory (Wholesalers, Jobbers, Dealers, etc.)

Veterinary biologics licensees or permittees must provide APHIS with a complete accounting of the inventory in the current possession of each wholesaler, jobber, dealer, consignee, or other person engaged in the distribution and sale of the serials or subserials subject to the APHIS stop distribution and sale action. These inventories can be transmitted electronically by these individuals to the licensee or permittees, who can then electronically transmit this information to APHIS. APHIS must have this information in order to successfully monitor the whereabouts of the biologics while they are being removed from distribution channels. In addition to inventory information, licensees and permittees must document – and submit to APHIS – any other communications they have with wholesalers, jobbers, dealers, consignees, or others concerning the stop distribution and sale action.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also, describe any consideration of using information technology to reduce burden.

The information collected in connection with this program may be submitted to APHIS via fax, or via email. No official VS forms are used in the collection of this information.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purpose described in item 2 above.

The information that APHIS is requesting is exclusive to its mission of preventing continued use of veterinary biological products that are ineffective or harmful. No other Federal agency is responsible for regulating veterinary biological products.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

The information APHIS is requiring is the absolute minimum needed to ensure that potentially harmful veterinary biologics do not cause harm to animals, the public health, or the environment. Electronic submission of this information should make this reporting task even less time-consuming. Under these circumstances, the Administrator of APHIS has determined that this action would not have a significant economic impact on a substantial number of small entities.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

Failing to require this information from licensees and permittees could result in the continued use of veterinary biologics products that are ineffective or harmful to animals.

7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with the general information collection guidelines in 5 CFR 1320.5.

- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**

Licensees and permittees must immediately, but no later than 2 days, send stop distribution and sale notices 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 preparations, distribution, sale, barter, exchange, shipment, or importation of any such veterinary biological product. All notification will be documented in writing by the licensee or permittee.

There are no other special circumstances associated with this information collection.

This project would be conducted in a manner consistent with the general information collection guidelines established in 5 CFR 1320.5.

8. Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting form, and on the data elements to be recorded, disclosed, or reported. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, soliciting comments on the information collection prior to submission to OMB.

In 2009, APHIS held productive consultations with the following individuals in connection with its system for promptly notifying wholesalers, dealers, jobbers, consignees, and other persons that a stop distribution and sale order has occurred:

Mr. Joseph O'Donnell
IDEXX Laboratories
One IDEXX Drive
Westbrook, ME 04092
Joe-O'donnell@idexx.com

Mr. Michael Waites
Merial Select, Inc.
P.O. Drawer 2497
Gainesville, GA 30503-2497
michael.waites@merial.com

Mr. David E. Carney
Colorado Serum Company
4950 York Street
Denver, CO 80216-0428
dcarney@colorado-serum.com

On Friday, August 7, 2009, page 39610, APHIS published in the Federal Register, a 60-day notice seeking public comments on its plans to request a 3-year renewal of this collection of information. Two comments from the public were received.

The two comments were received from the same concerned citizen in NJ about her perception of the general maltreatment of animals by USDA. These comments have no relevance to the purpose of the collection.

9. Explain any decision to provide any payment or gift to respondents, other than reenumeration of contractors or grantees.

This information collection activity involves no payments or gifts to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

No additional assurance of confidentiality is provided with this information collection. However, the confidentiality of information is protected under 5 U.S.C. 552a.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior or attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

This information collection activity will ask no question of a personal or sensitive nature.

12. Provide estimates of the hour burden of the collection of information. Indicate the number of respondents, frequency of response, annual hits burden, and an explanation of how the burden was estimated.

•Indicate the numbers of respondents, frequency of response, annual hits burden, and an explanation of how the burden was estimated. If this request for approval covers more than one form, provide separate hits burden estimates for each form and aggregate the hits burdens in Item 13 of OMB Form 83-I.

See APHIS Form 71 for burden hour estimates. Burden estimates were developed from discussions with veterinary biologics licensees and permittees, with wholesalers, jobbers, dealers, consignees, and other persons; and with State and Federal personnel engaged in the regulation of veterinary biologics.

•Provide estimates of annualized cost to respondents for the hits burdens for collections of information, identifying and using appropriate wage rate categories.

Respondents are veterinary biologics licensees and permittees, as well as certain wholesalers, jobbers, dealers, consignees, or other persons who must provide inventory data to licensees or permittees in the event of a stop distribution and sale order. APHIS estimates the total annualized cost to these respondents at $5,132. APHIS arrived at this figure by multiplying the hours of estimated response time (106) by the estimated average hourly wage of the above respondents ($48.41). $48.41 is the hourly rate derived from the U.S. Department of Labor; Bureau of Labor Statistics May 2008 Report - Occupational Employment and Wages in the United States. See http://www.bls.gov/news.release/ocwage.t03.htm

13. Provide estimates of the total annual cost burden to respondents or recordkeepers resulting from the collection of information (do not include the cost of any hits burden shown in items 12 and 14). The cost estimates should be split into two components: (a) a total capital and start-up cost component annualized over expected useful life; and (b) a total operation and maintenance and purchase of services component.

There is zero annual cost burden associated with capital and start-up costs, operation and maintenance expenditures, and purchase of services.

14. Provide estimates of annualized cost to the Federal government. Provide a description of the method used to estimate cost and any other expense that would not have been incurred without this collection of information.

The annualized cost to the Federal Government is estimated at $6,176.
(See APHIS Form 79.)

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-1.

The number of respondents has decreased from 60 to 55 respondents. This is because APHIS is no longer counting 5 of the respondents twice. There is no change in burden, merely a bookkeeping change to consolidate IC's.

16. For collections of information whose results are planned to be published, outline plans for tabulation and publication.

APHIS has no plans to publish information it collects in connection with this program.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

There are no forms associated with this collection.

18. Explain each exception to the certification statement identified in "Certification for Paperwork Reduction Act."

APHIS can certify compliance with all provisions under the Act.

B. Collections of Information Employing Statistical Methods

Statistical methods will not be used in connection with this project.