May 2018

SUPPORTING STATEMENT
VIRUSES, SERUMS, TOXINS, AND ANALOGOUS PRODUCTS:
RECORDS AND REPORTS
OMB NO. 0579-0209

TERMS OF CLEARANCE: "OMB is withholding approval at this time. Prior to publication of the final rule, the agency should provide a summary of any comments related to the information collection and their response, including any changes made to the ICR as a result of comments. In addition, the agency must enter the correct burden estimates." A summary of the comments is provided in Question 8 with one resulting in a change to the burden estimates for this information collection. Q15 and APHIS Form 71 explain and reflect the changes.

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 (VST) Act (21 U.S.C. 151-159) gives the U.S. 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. Veterinary biological products are 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).

To fulfill its mission of preventing the importation, preparation, sale, or shipment of harmful veterinary biological products, the Policy, Evaluation, and Licensing Unit of the Center for Veterinary Biologics (CVB), Veterinary Services, Animal and Plant Health Inspection Service (APHIS), issues licenses to qualified establishments that produce veterinary biological products, and issues permits to importers seeking to import such products into the United States. APHIS also enforces regulations concerning production, packaging, labeling, and shipping of veterinary biological products, and sets standards for the testing of these products. These regulations ensure that veterinary biological products used in the United States are not worthless, contaminated, dangerous, or harmful.

The VST Act also contains requirements for maintaining detailed records of information necessary to give a complete accounting of all the activities within a veterinary biologics establishment. These records include records and reports for unfavorable or unintended events that occur in animals after the use of a biological product. To limit the harm to animals posed by unsatisfactory veterinary biologics, APHIS must rely on adverse event reports (AER) provided by veterinary biologics licensees and permittees. (Non-licensees and non-permittees may submit reports, but are not required to do so.) However, without any explicit guidance as to the form those reports should take, licensees and permittees are using nonstandardized methods to record and submit reports regarding

adverse events to APHIS. Similarly, without explicit reporting requirements concerning adverse events, reports that may signal problems concerning the use of veterinary biological products are not all being submitted to APHIS in a timely manner.

APHIS amended the regulations to require licensees and permitees to submit adverse event reports.

The information APHIS obtains through the following documents enables it to ensure veterinary biological products used in the United States are pure, safe, potent, and effective. APHIS is asking the Office of Management and Budget (OMB) to approve its use of these information collection activities for 3 years.

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.

APHIS uses the following information activities to prevent the importation, preparation, sale, or shipment of harmful veterinary biological products and ensure that veterinary biological products used in the United States are not worthless, contaminated, dangerous, or harmful.

Adverse Event Report and Report Follow-Up (APHIS Forms 2080 and 2081); (9 CFR 116.9); (Businesses, Individuals, and States)

As part of the CVB's pharmacovigilance program, manufacturers, veterinarians, and animal owners use APHIS Form 2080 to collect information required of an adverse event report (AER) following the use of licensed veterinary biologics. This form captures information consistent with global Veterinary International Conference on Harmonization (VICH) standards. APHIS gives the APHIS Form 2081 follow-up report to submitters providing additional information after submitting the initial AER to CVB. Both of these forms collect information on the purity, safety, potency, and effectiveness of licensed veterinary biologics distributed in the United States and include submitter information, product information, detailed descriptions of events, suspected adverse event date(s), and reporter information.

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.

Authorized users may submit the information described in these forms electronically through the Center for Veterinary Biologics website. The forms will also be available for download from the APHIS forms website at https://www.aphis.usda.gov/aphis/resources/forms/ct_aphis_forms. Downloaded forms may be completed and mailed to APHIS.

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 APHIS collects for this program is exclusive to its mission of preventing the importation, preparation, sale, or shipment of harmful veterinary biological products. Separate from the Food and Drug Administration (FDA) which regulates veterinary pharmaceuticals (drugs used for the treatment of disease in animals), APHIS regulates an entirely different category of products (vaccines) that aid in preventing disease in animals by stimulating the immune system. APHIS and FDA have distinct regulatory missions that do not result in overlapping information collection activities.

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

More than 95 percent of the business respondents are small businesses or other small entities. The information APHIS collects is the minimum needed to ensure harmful veterinary biologics are not imported, prepared, or sold in the United States. Most of the required information already exists electronically or can be easily assembled and emailed to APHIS.

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 collect this information would severely cripple APHIS' ability to prevent harmful veterinary biologics from being distributed in the United States. The use of worthless or contaminated products and the resulting adverse effects could seriously undermine consumer confidence in the effectiveness and safety of these products, harming the U.S. economy and the veterinary biologics industry.

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 report information to the agency more often than quarterly;**

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

  Adverse event reports must be reported within 3 business days of a reportable event. This special circumstance ensures a timely response for preventing the dissemination of worthless, contaminated, dangerous, or harmful veterinary biologics.

- **requiring respondents to submit more than an original and two copies of any document;**

- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than 3 years;**

- **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**

- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**

- **that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**

- **requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

No other special circumstances exist that would require this collection to be conducted in a manner inconsistent with the general information collection guidelines 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.

APHIS engaged in productive consultations with the following individuals concerning the information collection activities associated with this program:

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APHIS' proposed rule, Docket No. APHIS-2014-0063, was published in the Federal Register on Friday, September 4, 2015, with a 60-day comment period. During this time, four commenters provided feedback. Their concerns and recommendations are addressed in depth in the Federal Register final rule notice published on May 17, 2018.

One comment was an affirmation the current system for detecting safety issues with products has historically worked well. The commenter did not believe there have been significant safety issues that have not been detected in a timely fashion.

Other commenters recommended refinement of term definitions, further or increased interaction with the VICH and industry to determine and harmonize standards, and removing the adverse event reporting restrictions on the licenses for conditionally licensed products. APHIS intends to engage with State veterinarians and other public groups to advise them of the availability of adverse event reports on the APHIS website. However, it will not remove adverse reporting restrictions on licenses because there may be specific issues associated with a product that require clarification on the license. One commenter asked for clarification on the maintenance of data and inspection results. The answer was in the proposed and final rule.

One commenter recommended postponing rule implementation until APHIS has the capability to receive submissions electronically. APHIS agrees on the importance of electronic submission and will prioritize the development of an electronic submission portal. However, as noted by another commenter, the current system for detecting safety signals with products has historically worked well. APHIS has, and will continue to have, the capability to receive adverse event information by phone, fax, email, etc. Another commenter pointed out that the same adverse event may be reported separately by two or more parties, such as the veterinarian and animal owner. APHIS agreed and will develop internal systems to detect duplicate reports. Two commenters recommended the term "immediate" be quantified to mean 3 days and that APHIS eliminate the 15 business day reporting requirement and any use of the concepts of "product-related", "serious", and "expected" for case management timelines. APHIS adopted both recommendations in the final rule. One commenter explained that .33 hours to generate and submit an adverse event report was insufficient and suggested 4 to 6 hours instead. APHIS agreed to an adjustment and increased the hours per response to 1 to 3 hours (2 hour average). This change is reflected in this information collection request.

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. Any and all information obtained in this collection shall not be disclosed except in accordance with 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 questions 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 hour burden, and an explanation of how the burden was estimated.

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

  See APHIS Form 71. Burden estimates were developed from discussions with Veterinary Services biologics field and staff personnel, biologic product manufacturers, biologic importers and exporters, researchers, shippers of biological products, and Federal personnel engaged in the regulation of veterinary biologics.

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

  The 9,999 respondents are U.S. importers and exporters of veterinary biological products, shippers of veterinary biological products, State veterinary authorities, and operators of establishments that produce or test veterinary biological products or that engage in product research and development. APHIS estimates the total annualized cost to the above respondents to be $1,183,286. APHIS arrived at this figure by multiplying the hours of estimated response time (31,998 hours) by the estimated average hourly wage of the above respondents ($36.98).

  The $36.98 average hourly rate was derived from the U.S. Department of Labor, Bureau of Labor Statistics May 2017 Report - Occupational Employment and Wages in the United States. (See http://www.bls.gov/news.release/pdf/ocwage.pdf: Importers and exporters $44.24 [Sales Representatives, Wholesale and Manufacturing, Except Technical and Scientific Products], Shippers $16.25 [Shipping, Receiving, and Traffic Clerks], State Animal Health

Authorities: $48.81 [Veterinarians], and Owners/Operators: $38.62 [Farm, Ranch, and Other Agricultural Managers].

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 hour 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 its expected useful life; and (b) a total operation and maintenance and purchase of services component.

No annual cost burden is associated with capital and startup 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.

See APHIS Form 79. The annualized cost to the Federal Government is estimated at $465,685.

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

	Requested	Program Change Due to New Statute	Program Change Due to Agency Discretion	Change Due to Adjustment in Agency Estimate	Change Due to Potential Violation of the PRA	Previously Requested
Annual Number of Responses	15,999	0	0	0	0	15,999
Annual Time Burden (Hours)	31,998	0	26,718	0	0	5,280
Annual Cost Burden ($)	0	0	0	0	0	0

This information collection reports 31,998 burden hours, an increase of 26,718 hours from the previous submission. APHIS adopted a recommendation from a commenter requesting an increased response time and changed it from .33 hours to 2 hours per response for each activity.

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

APHIS publishes a list of licensed establishments and licensed biological products on its website at http://www.aphis.usda.gov/animal_health/vet_biologics/publications/CurrentProdCodeBook.pdf. APHIS also publishes an annual report on its website for the public on the annual doses of biological products produced and destroyed.

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.

Not applicable. APHIS will display the expiration date.

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

APHIS can certify compliance with all provisions under the Act.

B. Collections of Information Employing Statistical Methods

There are no statistical methods associated with the information collection activities used in this program.