SUPPORTING STATEMENT 0579-XXXX
VIRUSES, SERUMS, TOXINS, AND ANALOGOUS PRODUCTS; PACKAGING AND LABELING

2016

Note: APHIS published a proposed rule in Federal Register on Thursday, January, 13, 2011 which stated it contained no paperwork burden. Then, after further review, paperwork was identified. To account for this paperwork, APHIS published a separate 60-day notice in the Federal Register on Friday, October 2, 2015. No comments were received from the public on the separate 60-day notice on paperwork; however, 6 comments were received on the proposed rule and all of which are addressed in the final rule. The final rule published on Tuesday, August 30, 2016.

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 when used according to label instructions.

The regulations in 9 CFR part 112, Packaging and Labeling, prescribe requirements for the packaging and labeling of veterinary biological products including requirements applicable to final container labels, carton labels, and enclosures. The main purpose is to regulate the packaging and labeling of veterinary biologics in a comprehensive manner, which includes ensuring that labeling provides adequate instructions for the proper use of the product, including vaccination schedules, warnings, and cautions. Complete labeling (either on the product or accompanying the product) must be reviewed and approved by APHIS in accordance with the regulations prior to use. As such, licensees and permitees must complete, and submit to APHIS, the transmittal of labels and circulars or outlines form, maintain label records, and provide written authorization statements from foreign veterinary officials of the importing country stating that the labels for export comply with the

requirements of their country (importing country), but do not comply with APHIS regulations for packaging and labeling.

The information APHIS obtains 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 to approve its use of this information collection activity 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:

9 CFR 112-113 - Transmittal of Labels and Circulars or Outlines (APHIS Form 2015) (reporting and recordkeeping) – business

Reporting
APHIS regulations require that labels used with veterinary biological products prepared at licensed establishments or imported for general distribution or sale must be reviewed, by APHIS, for compliance with USDA regulations and approved, in writing, before use. Our regulations also stipulate that an Outline of Production must be on file with APHIS for each licensed product or for each biological product authorized to be imported into the United States for distribution and sale.

Further, labels for export that comply with the requirement of the importing country but do not comply with APHIS regulations may also be submitted for approval using this form. The licensee should also provide written authorization from the regulatory officials of the importing country. APHIS Form 2015 provides the manufacturer or importer of the product with an orderly and standardized method for transmitting information regarding the numbers and types of labels and circulars, as well as the Outline of Production, to APHIS.

Recordkeeping
Each licensee and permittee must maintain a list of all approved labels currently being used. The inventory records must account for all labels printed including the disposition of those not used in labeling a product, and should be kept current for the entire period that a product remains in production. These records must be kept for 2 years from the expiration date of an experimental product. Each label must be identified as to (1) the name and product code number as it appears on the product license or permit for the product; (2) where applicable, the size of the package (dose by ml, cc, or units) on which the label will be used; (3) the label number and date assigned; and (4) the name of the licensee or subsidiary appearing on the label as the producer. The requirement for translations of non-English labels and affirmation of those translations is already included in APHIS regulations at 9 CFR 112.5(e).

9 CFR 112-113 - Written Authorization Statement (reporting) - foreign federal government

As noted above, for labels for export that don't comply with APHIS regulations, but comply with the regulations of the importing country – the government of the importing country must provide to the importer/export a written statement authorizing and affirming that the labels meet their standards.

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 written authorization statement can be electronically received or transmitted with the APHIS Form 2015. APHIS Form 2015 is available on the APHIS Web site in a fillable format. http://www.aphis.usda.gov/library/forms/pdf/APHIS_2015.pdf

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 collects in connection with this program is exclusive to its mission of preventing the importation, preparation, sale, or shipment of harmful veterinary biological products. The Food and Drug Administration (FDA) regulates veterinary pharmaceuticals (drugs used for the treatment of disease in animals), while APHIS regulates an entirely different category of products (vaccines) that aid in the prevention of disease in animals through stimulation of the immune system. APHIS and FDA, therefore, 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.

The information APHIS collects is the minimum needed to ensure that harmful veterinary biologics are not imported, prepared, or sold in the United States. Burden is minimized by the fact that most of the information APHIS requires already exists in an electronic format and can be easily assembled and emailed to APHIS. Approximately 50 percent of the respondents are small businesses or other 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 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;**
- **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 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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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.

Respondents are U.S. importers and exporters of veterinary biological products and foreign veterinary authorities. APHIS estimates the total annualized cost to the above respondents to be $7,187. APHIS arrived at this figure by multiplying the hours of estimated response time (180 hours) by the estimated average hourly wage of the above respondents ($39.93).

Importers and exporters $31.63 [Sales Representatives, Wholesale and Manufacturing, Except Technical and Scientific Products]
Foreign animal health authorities $48.23 [11-0000 Management Occupations]

$39.23 is the average hourly rate derived from the U.S. Department of Labor, Bureau of Labor Statistics May 2014 Report - Occupational Employment and Wages in the United States. See http://www.bls.gov/news.release/pdf/ocwage.pdf

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.

The annualized cost to the Federal Government is estimated at $4,426. (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.

This is a new information collection resulting in 180 total burden hours.

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 Web site at http://www.aphis.usda.gov/animal_health/vet_biologics/publications/CurrentProdCodeBook.pdf

APHIS also publishes an annual report on its Web site 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.

Upon approval of this information collection, the only official form included in this information collection package would be approved by two different information collection packages thus having two contradicting expiration dates. However, APHIS plans to merge this information collection into the “other” information collection - 0579-0013 at a later date/when appropriate.

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.