SUPPORTING STATEMENT 0579-0013
VIRUS-SERUM-TOXIN ACT AND REGULATIONS

October 2014

TERMS OF CLEARANCE: In accordance with the terms of 5 CFR 1320, OMB approves this collection of information for a period of 18 months. During that time, APHIS should develop a plan by which the forms associated with this collection can be submitted electronically. During that period, APHIS should also take into consideration the public comments received on this collection and determine whether it is feasible to waive the requirements for minor changes to labels, as suggested, or to perform additional inspections.

When submitting this collection for re-approval, APHIS should also submit a written response to these issues.

Currently, APHIS Form 2005 can be submitted electronically. APHIS Forms 2001, 2003, 2007, 2008, 2008A, 2015, 2017, 2018, 2046, 2046S, 2047, 2047S, 2048, 2049, 2020, 2070, 2071, and 2072, are PDF fillable and available on the APHIS web page for electronic completion. APHIS is developing a digital signature infrastructure to allow electronic forms to be digitally signed; which will enable the regulated industry to sign and submit these forms electronically. Once the infrastructure is in place, APHIS will provide a written plan to the regulated industry on how to electronically submit the forms described in this information collection package. APHIS will initiate a project to pilot digital signatures by the end of FY 2014. We anticipate the completion of the pilot project and use of digital signatures by the end of FY 2015

Two comments were received regarding this collection. The first commenter recommended that APHIS streamline the approval of outlines of production by allowing changes that have no impact to product fit, form, function or final product quality to be considered minor and included in annual updates; instead of needing prior approval. The commenter also provided Guidance to the Industry published by the Food and Drug Administration (FDA).

For the most part the regulatory processes of APHIS and FDA cannot be interchanged. In fact the FDA guidance provided by the commenter resulted from a statutory change which provided requirements for making and reporting manufacturing changes. However the results of each regulatory process are the same; to ensure that products approved for commercial use will perform as indicated. Significant changes in product manufacture must be approved by APHIS prior to use, and in some cases accompanied by data which verifies that the resulting product will still be pure safe, potent and efficacious.

The overarching issue raised by this comment is that the review and approval process for veterinary biological products needs to be streamlined. APHIS agrees. APHIS continues to work with industry to streamline the review and submission process. In May 2013, the Center for Veterinary Biologics, as one of their Business Process Improvement initiatives, began a pilot project to streamline the licensing process by accepting data and other submissions via an electronic format. In September, 2013, this process was made available to the entire biologics industry. Further, several forms were developed and approved which will standardize the manner in which certain required data is submitted; therefore decreasing the time needed to review the data. Also, APHIS has drafted a proposed rule regarding labels which has cleared OMB review. While not driven solely by this comment, this proposed rule should simplify certain aspects of the review process.

The second comment urges an immediate follow-up inspection of facilities where unsafe product was produced to ensure that any Animal Welfare Act (AWA) violations that accompany the identification of unsafe products are identified and corrected.

Appropriated funds, as well as this information collection, are approved and permitted in order for APHIS to enforce its responsibilities under the Virus, Serum and Toxin Act. Another program within APHIS is responsible for upholding and enforcing the Animal Welfare Act and receives appropriated funding specifically for these purposes.

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.

To enforce the regulatory requirements of the VST Act, APHIS must use a number of information gathering tools such as establishment license applications, product license applications, product permit applications, production and test report forms, and field study summaries.

Under APHIS' regulations at 9 CFR 105.3(a), CVB 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 quickly notify anyone who may be in possession of such products that a stop distribution and sale action has occurred. Any delay in notification increases the risk that these products could cause harm to animals, the public health, or 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, licensees 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.

The information APHIS obtains through these documents enables it to ensure that 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 an additional 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.

Application for U.S. Veterinary Biologics Establishment License (includes plot plans and blueprints) (APHIS Form 2001)
The prospective owner or operator (whether a corporation, partnership, or individual) of a veterinary biologics establishment uses APHIS Form 2001 to apply for a U.S. Veterinary Biologics Establishment License. Such establishments must meet minimum standards for facilities and production methods. Information contained on this application includes the name, address, and mailing address of the applicant; if a corporation or other entity, the name, title, and business address of the principal officers or partners; and the locations to be used for preparation, testing, and initial shipping. The information collected on Form 2001 allows APHIS to determine that the conditions of the facilities and the method of preparation of the product are likely to accomplish the intended purpose.

Application for U.S. Veterinary Biologics License (APHIS Form 2003)
The establishment owner or operator uses this form to apply to APHIS for a license to prepare any given biological product. Information contained on this application includes the name, address, and telephone number of the applicant; the type and quantity of veterinary biological product that will be prepared; and the location of the premises that will be used for such production.

Application for U.S. Veterinary Biologics Product Permit (APHIS Form 2005)
APHIS is authorized to issue three types of permits for importing veterinary biological products. They are (1) a Biological Product Permit for Research and Evaluation, (2) a Biological Product Permit for General Sale and Distribution, and (3) a Biological Permit for Transit Shipment Only. The APHIS Form 2005 is the application that the importer completes (with much the same information as on the 2001 and 2005, as well as storage location and shipping information, as appropriate) and submits to APHIS to apply for any of these permits.

Qualifications of Veterinary Biologics Personnel (APHIS Form 2007)
APHIS regulations require that licensed establishments be operated under the direct supervision of a person competent by education and experience to handle all matters pertaining to the preparation and testing of veterinary biological products. Data on this form, which is completed by the establishment's owner and operator and includes names and addresses of all schools attended and all biologics establishments of employment (as well as subjects studied and work performed), gives APHIS a biographical summary of each designated person responsible for any phase of preparation of a biological product.

Transmittal of Labels and Circulars or Outlines (APHIS Form 2015)
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. 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 us.

Official Export Certificate for Animal Biological Products (APHIS Form 2017)
Some foreign countries require U.S. exports to be accompanied by an Official Export Certificate for Animal Biological Products. This form provides official certification by APHIS that the products have been produced and tested in approved, inspected facilities according to specific manufacturing standards, and are therefore safe. APHIS Form 2017 is used by U.S. exporters to request this certification from APHIS. The form requires the name and address of the consignor and consignee as well as product name and number and container information.

Request for Reference, Reagent, or Reagent Seed Material (APHIS Form 2018)
CVB uses the APHIS Form 2018 to process and document any shipment of reagents (chemicals, cultures, cells, or other materials) used in the production or testing of veterinary biological products. The 2018 has three separate sections that must be completed:

- **The Request Section** of the form is completed by the individual requesting the reagents, and asks for the name, mailing address, and telephone number of the requesting firm; the date of the request; the firm’s license or permit number; the type of reagent requested and the quantity; the name of the courier and the courier’s account number; the name and title of the individual making the request; and that individual’s signature.

- **The Reply Section** of the form is completed by CVB personnel and specifies the number of containers, the volume of each container, the name of the shipper, whether the product needs refrigeration, the shipment date, the name and title of the CVB official processing the form, and the official’s signature.

- **The Receipt Section** of the form is completed by the individual who receives the shipment (usually the individual who requested the shipment) and asks for the number of containers,

the condition of the shipment, the date received, the name and title of the individual who received the shipment, and that individual's signature.

The APHIS Form 2018 documents that a shipment of reagents has been requested and received by a veterinary biologics manufacturing firm and allows APHIS to monitor the shipment to ensure that the same number of containers ordered by the firm were actually delivered to that firm and not diverted to another location for other uses.

Shipment and Receipt of Biologics Samples (APHIS Form 2020)
APHIS regulations require that manufacturers or importers give APHIS samples of serials and sub-serials of a biological product manufactured in the United States or imported into the United States. APHIS Form 2020, which is completed by the manufacturer or importer, ensures that each submission of samples to an APHIS laboratory includes the information necessary for APHIS to conduct the appropriate tests, and that the samples have been selected in accordance with APHIS regulations. The necessary information includes the date submitted; the name, address, and license number of the submitting firm; the purpose of the submission; shipment and sample container information; and the product name, code, and serial number.

Veterinary Biologics Production and Test Report (APHIS Form 2008 and Form 2008A)
No serial or sub-serial of a biological product is eligible for release for distribution and sale before completing tests prescribed by APHIS regulations. The APHIS Forms 2008 and 2008A are completed and submitted by the manufacturer to document the completion of all required tests. Information listed on this form includes the licensee's or permittee's name and mailing address, the product name and serial number, and test dates and results. This form must be submitted to APHIS before the release of the serial or sub-serial. This form is also used for requests to reprocess and rebottle a serial or sub-serial.

APHIS uses these forms as its primary means of ensuring that veterinary biological products used in the United States are pure, safe, potent, and effective.

Certificate of Licensing and Inspection (APHIS Forms 2046, 2046S, 2047, and 2047S)
These are Certificates of Licensing and Inspection (the "S" identifies the Spanish-language version of these forms) in which APHIS attests to the current inspection status of veterinary biologics establishments. Countries that import U.S. veterinary biologics frequently require U.S. manufacturers to give them this official certification before granting the manufacturer authorization to market such products in their country.

APHIS Forms 2046, 2046S, 2047, and 2047S make it easier for manufacturers to apply to APHIS for such certificates. The forms require the manufacturer to provide its name, address, and license number as well as the product's true name, trade name, USDA code, and date of licensure.

Application for Authorization to Ship Experimental Veterinary Biological Products (APHIS Form 2071)
For the benefit of license applicants and to permit and encourage research, a business may be authorized by APHIS to ship unlicensed biological products for the purpose of evaluating such experimental products by treating limited numbers of animals. However, APHIS must first

determine that the conditions under which the experiment is to be conducted are adequate to prevent the spread of disease. This form helps the manufacturer request this authorization and APHIS issue the authorization. This form does not represent a new information collection; it is a standardized method to collect information previously described under "Request for Authorization to Ship Unlicensed Biological Products for Experimental Field Studies in the United States." It not only standardizes the authorization process for the manufacturer but also streamlines the approval process.

Individuals wishing to ship unlicensed biological products to foreign countries for the purpose of evaluating such experimental products must, in addition to submitting information to APHIS, submit identical information (also using this form) to veterinary authorities in the foreign country where the experimental activity is to occur. This information will allow foreign veterinary authorities to determine whether to grant or deny the applicant's request to test unlicensed, experimental biological products in that country.

Application for Authorization to Ship Master Seed or Cell Samples for Confirmatory Testing by APHIS (APHIS Form 2070)
APHIS regulations require manufacturers to produce biological products from an APHIS-approved Master Seed or Cell. The Master Seed or Cell is extensively tested for purity and identity before approval. Part of this evaluation involves confirmatory testing by APHIS. This form helps manufacturers request permission to ship seed or cell samples to APHIS for confirmatory testing and helps APHIS provide this authorization. This form does not represent a new information collection; it is a standardized method to collect information already provided by manufacturers. It not only standardizes the authorization process for the manufacturer but also streamlines the approval process.

Application for Authorization to Ship Biological Product Samples for Confirmatory Testing by APHIS (APHIS Form 2072)
As part of the pre-license evaluation, or whenever manufacturers wish to change their production process for a licensed product, APHIS may elect to perform confirmatory testing on product samples. This form helps manufacturers request permission to ship product samples to APHIS for confirmatory testing and helps APHIS provide this authorization.

Request for Restriction on Distribution and Use of a Veterinary Biological Product
Any person may request that the distribution and use of a veterinary biological product be restricted if the restriction pertains to the protection of domestic animals or public health, interest, or safety. All requests must be sent to the CVB director in writing. Requests must specify the restrictions being requested and must explain why the restrictions are needed. Copies of any supporting documents, such as scientific literature, published or unpublished articles, or data from tests, must be attached to the request.

Petition for Reissue of Conditional License
To meet an emergency condition, limited market, local situation, or other special circumstance, including production solely for intrastate use under a State-operated program, APHIS may issue a conditional U.S. Veterinary Biological Product License to an establishment under an expedited

procedure which assures purity and safety, and a reasonable expectation of efficacy. Preparation of products under a conditional license may be limited to a predetermined time period established at the time of issuance. Before termination of the license, the licensee may request reissuance. These requests must be substantiated with data and information obtained since the license was issued.

Application to Produce Experimental Products
APHIS may authorize the preparation of experimental products on the premises of a licensed establishment if it determines that such preparation will not contaminate licensed products. Each request for permission to prepare an experimental biological product on a licensed premise must indicate the nature of the unlicensed product, designate facilities to be used, and specify precautions that will be taken to prevent contamination of licensed products.

Show Intent to Resume Production
If a biological product has not been prepared by a licensee, or imported by a permittee, for a period of 5 years or more, APHIS may require the licensee to show intent to resume production, or may require the permittee to show intent to resume importation. If the licensee does not resume preparation, or the permittee does not resume importation, within 6 months of being notified by APHIS (or within a mutually agreeable period), APHIS may terminate the product license or permit. Intent to resume preparation or importation can be accomplished in writing or via email.

State Notifies APHIS of each Establishment and Product License Issued or Terminated
For products and establishments under State license, each biological product and each establishment preparing such product must be identified and reported to APHIS by the State that issues the license for that product or establishment. The State must also provide written notice to APHIS whenever it issues or terminates a product or establishment license.

List of Approved Labels Currently Being Used
A licensee or permittee must submit to APHIS, on request, a list of all approved product labels currently being used. Each label listed 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 (doses, 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.

Request for Authorization to Prepare an Autogenous Biologic for Use in Herds Adjacent to the Herd of Origin
Under normal circumstances, microorganisms from one herd must not be used to prepare an autogenous biologic for another herd. APHIS, however, may authorize preparation of an autogenous biologic for use in herds adjacent to the herd of origin when adjacent herds are considered to be at risk. To request authorization to prepare a product for use in herds adjacent to the herd of origin, the establishment seeking authorization must maintain the following records as required in 9 CFR 113.113 for review by CVB, Inspection and Compliance (IC), during onsite inspections: (1) the name, address, and phone number of the owner of the herd of origin; (2) the attending veterinarian's name, address, and phone number; (3) the species and number of animals in the herd of origin; (4) identification of the microorganisms, at least to genus; (5) the diagnosis or clinical signs of the disease observed; (6) the name and address of the person who isolated the microorganisms and the date of isolation; (7) the number of doses of autogenous biologic requested and vaccination

schedule; (8) each adjacent herd owner's name, address, and phone number; (9) the number and species of animals in each adjacent herd; and (10) the attending veterinarian's or approved specialist's assessment of the involvement of the adjacent herds with the disease observed. The applicant must also notify the State veterinarian or other appropriate State official when an autogenous biologic is to be used in adjacent herds.

Request to Use an Isolate Beyond the Time Limit Prescribed
Under normal circumstances, microorganisms used for the production of autogenous biologics may not be older than 24 months from the date of isolation, or 12 months from the date of harvest of the first serial of product produced from the microorganisms, whichever comes first. APHIS, however, may authorize production of additional serials from microorganisms older than the above stated time periods if the business submits in writing certain information to the CVB-IC director, including: (1) the attending veterinarian's or approved specialist's current assessment of the continued involvement of a herd with the originally isolated microorganisms, including a summary of the diagnostic work supporting this assessment; (2) evidence of satisfactory protection from the previous use of the autogenous biologic produced from the microorganisms involved; and (3) any other information APHIS may require to determine the need to use the microorganism to make additional serials.

Protocol and Additional Testing Requirements for Autogenous Biologics
Persons seeking authorization to prepare additional serials of autogenous biologics from microorganisms older than 24 months from the date of isolation must test the completed product for antigenicity or immunogenicity in the species for which the product is recommended or in another animal species whose immunological response has been shown in the scientific literature to correlate with the response of the species for which the product is recommended. These tests must be conducted in accordance with an APHIS-approved protocol developed by the licensee. The licensee must submit the test results, in writing, to the CVB-PEL director for review.

Request for Extension of Expiration Date for a Serial or Subserial
The CVB-IC director may grant an extension of the expiration date for a serial or subserial of a veterinary biologic on written request from the licensee if the request is substantiated by valid test data demonstrating that the product's potency meets or exceeds the requirements for release.

Reports on Activities (Inspection and Compliance E-Submission Form - APHIS Form 2048 and Policy, Evaluation, and Licensing E-Submission Form 2049)
When required by APHIS, the licensee, permittee, or foreign manufacturer whose products are being offered for importation must prepare and submit written reports containing accurate and complete information concerning biological products (including but not limited to product development and preparation as well as market suspensions and recalls) to the CVB-PEL director. These entities must also provide copies of these documents in the following situation:

- **Submit Summary of Field Studies**
  Applicants requesting APHIS authorization to ship unlicensed biological products for experimental field studies must, on conclusion of the field studies, summarize and submit the results of the studies to APHIS.

Inspection and Compliance E-Submission Form (APHIS Form 2048) – Previously this item was not an official form but this information was collection under the title "Reports on Activities". APHIS is not seeking any new or additional information from previous submission.

APHIS is moving toward electronic submissions of OMB approved forms and supplementary information associated with this information collection. This form will be the basis for electronic submission from respondents of previously OMB cleared information collection data via an authenticated portal. For now, this form provides specific information to facilitate receipt of electronic submissions in CVB Inspection and Compliance and entry into the current document tracking system. This form ensures all the needed information is provided, in a manner that can directly be transcribed into our document tracking system. This form does not represent a new information collection; it is a standardized method to collect information already provided by manufacturers.

Policy, Evaluation, and Licensing E-Submission Form (APHIS Form 2049) - Previously this item was not an official form but this information was collection under the title "Reports on Activities". APHIS is not seeking any new or additional information from previous submission.

APHIS is moving toward electronic submissions of most forms and other information associated with this information collection. This form will be the basis for electronic submission of data via an authenticated portal. For now, this form provides specific information to facilitate entry into the current document tracking system. It replaces information that traditionally has been provided in a cover letter written by the submitter. This form ensures all the needed information is provided, and in a manner that can directly be transcribed into our document tracking system. This form does not represent a new information collection; it is a standardized method to collect information already provided by manufacturers.

Patent Term Restoration Letter of Application for Extending the Term of a Veterinary Biologic Patent

Licensees and permittees must submit requests for extension of the term of a veterinary biologic patent to the Patent and Trademark Office (PTO) of the U.S. Department of Commerce. APHIS will help the PTO determine whether a patent related to a biological product is eligible for a term extension.

Request for Revision of the Regulatory Review Period

Not later than 30 days after receiving an application for extending the term of a veterinary biologic patent from the PTO, APHIS will determine the regulatory review period for the product. Any interested person may request a revision of the regulatory review period determination within the 30-day period beginning on its publication date in the *Federal Register*. This request must be submitted in writing to the CVB-PEL director and must specify (1) the identity of the product, (2) the identity of the applicant for patent term restoration, (3) the docket number of the *Federal*

Register notice announcing the regulatory review period determination, and (4) the basis for the request for revision, including any supporting documentary evidence.

Due Diligence Petition and Certification Statement of True and Complete Copy
Any interested person may file a petition with APHIS, no later than 180 days after the publication of a regulatory review period determination, alleging that a license applicant did not act with due diligence in seeking APHIS approval of the product during the regulatory review period. The petition must allege that the applicant failed to act with due diligence sometime during the regulatory review period and must set forth sufficient facts to merit an APHIS investigation. The petition must certify that the petitioner has served a true and complete copy of the petition on interested parties by certified or registered mail or by personal delivery.

Applicant's Response to Petition
The applicant may file with APHIS a written response to the petition no later than 20 days after the applicant's receipt of a copy of the petition. The applicant's response may present additional facts and circumstances to address the assertions in the petition, but must be limited to the issue of whether the applicant acted with due diligence during the regulatory review period. The applicant's response may include documents that were not in the original patent term extension application.

Request for Due Diligence Hearing
Any interested person may request, within 60 days beginning on the date of publication of a due diligence determination, that APHIS conduct an informal hearing on the due diligence determination. The request for a hearing must be submitted to APHIS and must contain (1) the docket number of the *Federal Register* notice of APHIS' regulatory review period determination; (2) a full statement of the facts on which the hearing request is based; (3) the name, address, and principal place of business of the person requesting the hearing; and (4) a certification that the person requesting the hearing has served a true and complete copy of the request on the petitioner of the due diligence determination and the applicant for patent term extension by certified or registered mail or by personal service.

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 involved in the APHIS stop distribution and sale action. This notification must be documented, in writing, and submitted to APHIS to verify 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 give APHIS 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 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.

RECORDKEEPING

Records of Disposition of Test Animals

Research investigators or research sponsors must maintain adequate records on the disposition of each animal administered experimental biological products. These records must be maintained for a minimum of 2 years from the date that an experimental product was administered to the animal, and must show the name and address of the owner; the number, species, class, and location of the animals; and, if sold, the name and address of the consignee, buyer, commission, firm, or abattoir.

Records of Exempt Biologics

Veterinarians preparing products subject to APHIS exemption for products must maintain and make available for inspection – by APHIS representatives or other Federal employees – any records necessary to establish that a valid veterinarian-client-patient relationship exists and that there is a valid basis for the exemption. These records must be kept for 2 years from the expiration date of an experimental product.

Sterilization and Pasteurization Records

Sterilizers or pasteurization equipment used for processing biological products, ingredients, or equipment at licensed establishments must be equipped with automatic temperature recording gauges or an equivalent accurate and reliable system. The business must make available charts and other temperature records made during production for APHIS inspection at all times. These records must be identified with the ingredients, equipment, or biological product subjected to sterilization or pasteurization. These records must be kept for 2 years from the expiration date of an experimental product.

Records of Antiserum or Serum Pasteurized

Blood derivatives (serum, plasma), lacteal secretions, and egg material used in the production of antibody products must be subjected to an appropriate procedure for the inactivation of potentially contaminating microorganisms. Licensees must keep detailed records on each batch treated and each serial of product prepared for marketing. Recording charts must bear full information concerning the material treated and tests made of the equipment used for treatment. These records must be kept for 2 years from the expiration date of an experimental product.

Records of All Tests

No biological product can be released before completing tests designed to establish that the product is pure, safe, potent, and efficacious. Records of all tests must be maintained, and test results must be submitted by the manufacturer to APHIS. Detailed records of all tests conducted on each serial and subserial must also be maintained by the licensee. Summaries of these tests must be submitted

to APHIS before the release of the serial or subserial. These records must be kept for 2 years from the expiration date of an experimental product.

Animal Records
Complete records must be kept for all animals at a licensed establishment. These records must be kept for 2 years from the expiration date of an experimental product. Results of tests performed, antigens or treatments administered, maintenance and production records, disposition records, necropsy records (if any), and all other pertinent records must be included.

Identity of the Mircoorganism
Veterinary biologics licensees must maintain a record of identity tests conducted on all microorganisms used for the production of autogenous biologics. Bacteria, fungi, and mycoplasma must be identified at least to genus and species. Viruses must be identified at least to family. After 15 months from the date of isolation, characterization and identification must be completed to strain and subtype. Records must be kept for 2 years after the expiration date of a product.

Records of Microorganisms Used
A complete record of the microorganisms used to prepare biological product at licensed establishments must be kept currently correct for the entire period that such microorganisms are maintained at the production facility. These records must be kept for 2 years from the expiration date of an experimental product.

Records of Production of Product, Inventory, and Disposition
Each licensee, permittee, and foreign manufacturer of biological products imported into the United States must maintain, at the licensed or foreign establishment in which the products are prepared, detailed records of information necessary to give a complete accounting of all activities within each establishment, including activities related to product production, inventory, and disposition. Records must be made concurrently with the performance of successive steps in the development and preparation of biological products, including new products under development. These records must include the date and, where critical, the time that each essential step was taken; the identity and quantity of ingredients added or removed at each step; and any gain or loss of product from the beginning to the end of product preparation. The records must be legible and indelible. They must contain enough detail to clearly explain each step to an individual experienced in the preparation of biological products, and they must be verified by initials or signature of the person immediately responsible for the action taken. Records (other than disposition records) must be completed by the licensee or the foreign manufacturer, as the case may be, before any portion of a serial or product can be marketed in the United States or exported. The records must be retained for 2 years after the expiration date of the product.

Label Records
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.

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.

Currently, APHIS Form 2005 can be submitted electronically. APHIS Forms 2001, 2003, 2007, 2008, 2008A, 2015, 2017, 2018, 2046, 2046S, 2047, 2047S, 2048, 2049, 2020, 2070, 2071, and 2072, are PDF fillable and available on the APHIS web page for electronic completion. APHIS is developing a digital signature infrastructure to allow electronic forms to be digitally signed; which will enable the regulated industry to sign and submit these forms electronically. Once the infrastructure is in place, APHIS will provide a written plan to the regulated industry on how to electronically submit the forms described in this information collection package. APHIS will initiate a project to pilot digital signatures by the end of FY 2014. We anticipate the completion of the pilot project and use of digital signatures by the end of FY 2015

Notification of wholesalers (licensees and permittees), accounting of inventory (licensees and permittees), and accounting of inventory (wholesalers, jobbers, dealers, etc.) may be submitted to APHIS via fax or email.

At this point all other information collection activities that do not involve official forms must be mailed to APHIS for the confidentiality and signature reasons listed above. Simple requests may be sent by email.

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. More than 95 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;**

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 veterinary biological product subject to an APHIS stop distribution and sale action in their possession. The notices instruct the jobbers, etc. to stop the preparation, distribution, sale, barter, exchange, shipment, or importation of any such veterinary biological product. All notifications are documented in writing by the licensee or permittee.

- **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 three 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.

On Tuesday, August 5, 2014, page 45422-45423, 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. There were no comments received.

In 2013, APHIS engaged in productive consultations with the following individuals concerning the information collection activities associated with this program:

Dr. Lisa Becton
National Pork Board
1776 NW 114th Street
Des Moines, IA 50325
515-223-2791
lbecton@pork.org

Mr. Normand Brown
Intervet Inc.
21401 West Center Road
Elkhorn, NE 68022
402-289 6070
Normand.brown@sp.intervet.com

Catherine Kerr
IDEXX Laboratories
One IDEXX Dr.
Westbrook, ME 04092
207-556-0300
Catherine-Kerr@IDEXX.com

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, 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 $2,266,024. APHIS

arrived at this figure by multiplying the hours of estimated response time (78,382 hours) by the estimated average hourly wage of the above respondents ($28.91).

Importers and exporters $26.16 [Sales Representatives, Wholesale and Manufacturing, Except Technical and Scientific Products]
Shippers $14.10 [Shipping, Receiving, and Traffic Clerks]
State Animal Health Authorities: $41.66 [Veterinarians]
Owners/Operators: $33.71 [Farm, Ranch, and Other Agricultural Managers]

$30.68 is the average hourly rate derived from the U.S. Department of Labor, Bureau of Labor Statistics May 2013 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 $1,329,334. (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.

N

There is no change in burden for this submission.

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.

APHIS has no plans to seek approval for not displaying the OMB expiration date on its forms.

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.