August 2018

**SUPPORTING STATEMENT**
**VIRUS-SERUM-TOXIN ACT AND REGULATIONS**
**OMB NO. 0579-0013**

**This is a reinstatement of a previously approved information collection with changes.**

**NOTE: This information collection combines 0579-0460 (Viruses, Serums, Toxins, and Analogous Products; Packaging and Labelling), and 0579-0209 (Viruses, Serums, Toxins and Analogous Products: Records and Reports), into 0579-0013 (Virus-Serum-Toxin Act and Regulations, 9 CFR Subchapter E, Parts 101-124) as all three address information collection activities are related to veterinary biological products. 0579-0209 and 0579-0460 will be discontinued upon approval of 0579-0013.**

**TERMS OF CLEARANCE: "APHIS should continue to develop a system that allows the forms associated with this collection to be submitted electronically. APHIS should continue to determine whether it is feasible to waive the requirements for minor changes to labels or to perform additional inspections."**

Currently, all of the forms used in this information collection can be submitted electronically through the National Centers for Animal Health (NCAH) Portal, ePermits, or completed as fillable PDF's.

APHIS has not yet determined whether it is feasible to waive the requirements for minor changes to labels or additional inspections. A labelling error for a veterinary biological product could result in the catastrophic losses of livestock administered the product. Reviews and inspections are critical tools for minimizing this risk.

## 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 101 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).

The Policy, Evaluation, and Licensing Unit of the Center for Veterinary Biologics (CVB), Veterinary Services, Animal and Plant Health Inspection Service (APHIS), uses a number of

information gathering tools to fulfill its mission of preventing the importation, preparation, sale, or shipment of harmful veterinary biological products. These activities enable APHIS to ensure that veterinary biological products used in the United States are pure, safe, potent, and effective. 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. APHIS is asking the Office of Management and Budget (OMB) to approve the reinstatement and 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, shipment, preparation, or sale of contaminated, dangerous, worthless, or harmful veterinary biological products within the United States.

**Application for U.S. Veterinary Biologics Establishment License (includes plot plans and blueprints) (APHIS Form 2001), (9 CFR 102.1, 9 CFR 108.2), (Business)**

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 APHIS 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.

**CVB Inspection and Compliance Facility Document Submission Worksheet (APHIS Form 2009), (9 CFR 102.1, 9 CFR 108.2), (Business), (New)**

The new APHIS Form 2009, Center for Veterinary Biologics (CVB) Inspection and Compliance Facility Document Submission Worksheet, was created to supplement the APHIS Form 2001. This form is a more efficient way for new and existing applicants to electronically submit documentation supporting their requests for an Establishment License or to update existing documents. The new form also helps applicants identify the documents they need to submit by using drop-down menus in the electronic form.

**Application for U.S. Veterinary Biologics License (APHIS Form 2003), (9 CFR 102.1), (Business)**

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.

**Certificate of Licensing and Inspection (APHIS Forms 2046, 2046S, 2047, and 2047S), (9 CFR 102.4), (Business)**

The APHIS Form 2046 and 2047 are Certificates of Licensing and Inspection in which APHIS attests to the current inspection status of veterinary biologics establishments. APHIS Form 2046S and 2047S are the Spanish-language versions of these forms. These 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. Countries that import U.S. veterinary biologics frequently require U.S. manufacturers to provide this official certification before receiving authorization to market their products in the country.

**Qualifications of Veterinary Biologics Personnel (APHIS Form 2007), (9 CFR 102.4, 9 CFR 114.7), (Business)**

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. This form is completed by the establishment's owner and operator, and includes the names and addresses of all schools they attended and all biologics establishments where they were employed (as well as subjects studied and work performed). It also provides APHIS a biographical summary of each designated person responsible for any phase of preparation of a biological product.

**Request for Restriction on Distribution and Use of a Veterinary Biological Product, (9 CFR 102.5), (Business)**

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 and must specify the restrictions being requested and an explanation or justification. Requests may include copies of any supporting documents such as scientific literature, published or unpublished articles, or data from tests.

**Petition for Reissue of Conditional License, (9 CFR 102.6), (Business)**

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, (9 CFR 103.1), (Business)**

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.

**Application for Authorization to Ship Experimental Veterinary Biological Products (APHIS Form 2071), (9 CFR 103.3), (Business)**

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. Manufactures request this authorization and APHIS issues it using APHIS Form 2071 which allows for a standardized and streamlined process. Shippers/applicants must provide their name and full mailing address; their U.S. veterinary establishment number, if applicable; the application type (new or amendment); a description of the product to be shipped; and the name and address of the recipient (including the address where the product is to be used, if different).

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 U.S. Veterinary Biologics Product Permit (APHIS Form 2005), (9 CFR 104.5), (Business)**

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. Importers apply for these permits using APHIS Form 2005. The form requests the same information found on APHIS Forms 2001 and 2005, plus storage location and shipping information.

**Show Intent to Resume Production, (9 CFR 105.4), (Business)**

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 Notification of each Establishment and Product License Issued or Terminated, (9 CFR 107.2, 9 CFR 114.2), (State)**

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.

**Package Labeling, (9 CFR 112.1, 9 CFR 112.2) (Business) (Third Party Disclosure), (New)**

Biologic product packaging and labels must contain certain information that accurately conveys to the consumer the contents of the container and the purpose of the product as well as its efficacy and

expiration date, if applicable, and lot numbers as well as other information prescribed in 9 CFR 112.3.

**Transmittal of Labels and Circulars or Outlines, Reporting (APHIS Form 2015), (9 CFR 112.2, 9 CFR 112.5, 9 CFR 112.9, 9 CFR 113.3, 9 CFR 113.47, 9 CFR 114.9), (Business), (Merger)**

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 be approved in writing before use. 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. An Outline of Production also 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. These requirements are initiated with APHIS Form 2015 which provides the manufacturer or importer of the product 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.

**Written Authorization Statement, Reporting, (9 CFR 112,2, 9 CFR 113.3), (Foreign Government), (Merger)**

As noted for Transmittal of Labels and Circulars or Outlines, Reporting (APHIS Form 2015) above, for labels for export that do not comply with APHIS regulations but do comply with the regulations of the importing country, the importer/exporter must be provided by the government of the importing country a written statement authorizing and affirming that the labels meet their standards.

**List of Approved Labels Currently Being Used, (9 CFR 112.5), (Business)**

A licensee or permittee must submit to APHIS, upon 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.

**Official Export Certificate for Animal Biological Products (APHIS Form 2017), (9 CFR 112.47, 9 CFR 112.69, 9 CFR 112.71), (Business)**

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. U.S. exporters prepare and submit APHIS Form 2017 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), (9 CFR 113, 9 CFR 114.4, 9 CFR 114.8, 9 CFR 114.9), (Business)**

APHIS Form 2018 is used to request, process, and document any shipment of reagents (chemicals, cultures, cells, or other materials) used in the production or testing of veterinary biological products. The form 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. The form 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 APHIS 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.

**Shipment and Receipt of Biologics Samples (APHIS Form 2020), (9 CFR 113.3), (Business)**
Manufacturers and importers must provide APHIS samples of serials and subserials of a biological product manufactured in the United States or imported into the United States. A manufacturer or importer must prepare APHIS Form 2020, ensuring 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. 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.

**Application for Authorization to Ship Biological Product Samples for Confirmatory Testing by APHIS (APHIS Form 2072), (9 CFR 113.3, 9 CFR 113.6), (Business)**
As part of the pre-license evaluation, or whenever manufacturers decide to change their production process for a licensed product, APHIS may elect to perform confirmatory testing on product samples. Manufacturers must submit APHIS Form 2072 to obtain permission to ship product samples to APHIS for confirmatory testing. The form requires the shipper/applicant name and full mailing address; U.S. veterinary establishment number, if applicable; the application type (new or amendment); the true names of the products to be shipped (with product code and serial number); the purpose for shipping; and a name, phone number, and email address for a contact at the shipping establishment.

**Veterinary Biologics Production and Test Report; Request for Reprocessing and Rebottling for a Serial or Subserial (APHIS Forms 2008 and 2008A), (9 CFR 113.5, 9 CFR 113.68, 9 CFR 113.69, 9 CFR 113.70, 9 CFR 113.71, 9 CFR 114.17, 9 CFR 114.18, 9 CFR 116.7), (Business)**
APHIS is responsible for ensuring veterinary biological products used in the United States are pure, safe, potent, and effective. No serial or subserial of a biological product is eligible for release for distribution and sale before manufacturers complete all tests prescribed by APHIS regulations and

submitting the results to APHIS using APHIS Forms 2008 and 2008A. The forms include the licensee's or permittee's name and mailing address, the product name and serial number, and test dates and results. The forms are used also for requests to reprocess and rebottle a serial or subserial.

**Application for Authorization to Ship Master Seed or Cell Samples for Confirmatory Testing by APHIS (APHIS Form 2070), (9 CFR 113.52, 9 CFR 113.100, 9 CFR 113.200, 9 CFR 113.300), (Business)**

Manufacturers must produce biological products from APHIS-approved master seeds or cells which are extensively tested for purity and identity, and confirmatory testing is conducted by APHIS. Manufactures request permission to ship seed or cell samples to APHIS using APHIS Form 2070. Applications include the company name and full mailing address; U.S. veterinary establishment number, if applicable; the application type (new or amendment); a description of the product to be shipped; and the name, phone number, and email address of a contact for the applicant. The applicant must also completely identify all seeds or cells being shipped (by baseline passage, high passage, or parental construct) and specify how the seeds or cells are to be shipped.

**Request for Authorization to Prepare an Autogenous Biologic for Use in Herds Adjacent and Not Adjacent to the Herd of Origin, (9 CFR 113.113), (Business)**

Under normal circumstances, microorganisms from one herd must not be used to prepare an autogenous biologic for another herd. However, APHIS 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 an autogenous biologic for use in herds adjacent to the herd of origin, the establishment seeking authorization must provide APHIS: (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, (9 CFR 113.113), (Business)**

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. However, APHIS may authorize production of additional serials from microorganisms older than these time periods if the business submits to the APHIS CVB-IC Director: (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, (9 CFR 113.113), (Business)**

Before additional serials of autogenous biologics from microorganisms older than 24 months from the date of isolation may be approved, the completed product must be tested 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, (9 CFR 114.14), (Business)**

Upon written request from the licensee, the CVB-IC Director may grant an extension of the expiration date for a serial or subserial of a veterinary biologic if the request is substantiated by valid test data demonstrating that the product's potency meets or exceeds the requirements for release.

**Wholesaler Notifications (Licensees and Permittees), (9 CFR 115.2), (Business)**

Immediately after being contacted by APHIS, veterinary biologics licensees or permittees must provide stop distribution and sale notifications 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 also 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.), (9 CFR 115.2(b)), (Business)**

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 may be transmitted by these individuals to the licensee or permittees who may then 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.

**Reports on Activities (APHIS Forms 2048 and 2049), (9 CFR 116.5), (Business)**

Licensees, permittees, or foreign manufacturers whose products are being offered for importation may be required to prepare and submit to the CVB-PEL Director 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). Applicants requesting APHIS authorization to ship unlicensed biological products for experimental field studies also must summarize and submit the results of the studies to APHIS upon conclusion of the field studies.

- **Reports on Activities (Center for Biologics Inspection and Compliance E-Submission Form) (APHIS Form 2048)**
  As a standardized method to collect information provided by manufacturers, this form allows respondents to electronically submit specific information to CVB Inspection and Compliance in a manner that can be transcribed directly into the document tracking system.

- **Reports on Activities (Veterinary Biologics Regulation and Policy, Evaluation, and Licensing E-Submission Form) (APHIS Form 2049)**
  As a standardized method to collect information provided by manufacturers, this form replaces a cover letter prepared by the submitter and allows respondents to electronically submit specific information in a manner that can be transcribed directly into the document tracking system.

**Patent Term Restoration Letter of Application for Extending the Term of a Veterinary Biologic Patent, (9 CFR 124.10, 9 CFR 124.20), (Business)**

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 assists the submitters and the PTO in determining whether a patent related to a biological product is eligible for a term extension.

**Request for Revision of the Regulatory Review Period, (9 CFR 124.22), (Business)**

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 and publish a notice in the Federal Register. Any interested person may request a revision of the regulatory review period determination during the notice's publication period. The 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, (9 CFR 124.30), (Business) (Individual)**

Not later than 180 days after the publication of a regulatory review period determination notice, any interested person may file a petition with APHIS 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 service.

**Applicant's Response to Petition, (9 CFR 124.31), (Business)**

An applicant may file with APHIS a written response to a petition no later than 20 days after receipt of a copy of the petition. The response may present additional facts and circumstances addressing 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, (9 CFR 124.40), (Business) (Individual)**
Within 60 days of publication beginning date of a due diligence determination notice, any interested person may request that APHIS conduct an informal hearing on the due diligence determination. The request for a hearing must be submitted to APHIS and 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.

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

**RECORDKEEPING**

**Records of Disposition of Test Animals, (9 CFR 103.2), (Business)**
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, (9 CFR 107.1), (Business)**
Veterinarians preparing products subject to APHIS exemption 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, (9 CFR 109.2), (Business)**
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 to APHIS inspectors at any time charts and other temperature records made during production. These records must be identified with the ingredients, equipment, or biological product subjected to sterilization or pasteurization; and must be kept for 2 years from the expiration date of an experimental product.

**Records of All Tests, (9 CFR 113.5, 9 CFR 113.6), (Business)**
No biological product can be released before completing tests designed to establish that the product is pure, safe, potent, and efficacious. Manufacturers must maintain records of all tests and submit test results to APHIS. Detailed records of all tests conducted on each serial and subserial must also be maintained by the licensee, with summaries of these tests 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.

**Records of Antiserum or Serum Pasteurized, (9 CFR 113.45), (Business)**
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.

**Identity of the Microorganism, (9 CFR 114.5), (Business)**
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, (9 CFR 114.5), (Business)**
A complete record of the microorganisms used to prepare biological products 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, (9 CFR 114.6, 9 CFR 115.1, 9 CFR 116.1, 9 CFR 116.2, 9 CFR 116.5, 9 CFR 116.8), (Business)**
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, (9 CFR 112.1, 9 CFR 116.3), (Business)**
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. 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). These records must be kept for 2 years from the expiration date of an experimental product.

**Animal Records, (9 CFR 116.6; 9 CFR 117), (Business)**
Complete records must be kept for all animals at a licensed establishment, and include results of tests performed, antigens or treatments administered, maintenance and production records, disposition records, necropsy records (if any), and all other pertinent records. These records must be kept for 2 years from the expiration date of an experimental product.

**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 Center for Veterinary Biologics (CVB) introduced the National Centers for Animal Health (NCAH) Portal as an public-facing, web-based application for biologics firms to electronically submit APHIS Forms 2001, 2003, 2007, 2008, 2018, 2020, 2048, 2049, 2070, 2071, and 2072. The NCAH Portal also enables firms to receive submission responses from CVB. Due to the confidential business information submitted to the CVB, access for CVB submissions is limited to the regulated industry. Users are required to have an APHIS Form 2007 on file with CVB and USDA Level 2 eAuthentication for security verification, and users only have access to their firm's submissions.

The NCAH Portal also accepts electronic submissions of outlines of production and special outlines. These submissions had previously been submitted in hard copy using APHIS Form 2015.

Each of these forms are also PDF fillable and available on the APHIS webpage for electronic completion. They and the outlines can be attached to APHIS Form 2049 and submitted via the NCAH Portal.

The NCAH Portal expansion also allowed electronic submission of veterinary biologic labels, which had previously been submitted hard copy by using APHIS Form 2015.

CVB is currently evaluating how submission of facility documents can be added to the NCAH Portal by using APHIS Form 2048. CVB is also studying the electronic submissions of fillable PDF APHIS Forms 2015, 2017, 2046, 2046S, 2047, and 2047S. CVB will continue to process paper submissions for regulated entities.

APHIS Form 2009 is a new form. It and APHIS Form 2015 are in fillable PDF.

APHIS Form 2005 may be is submitted electronically through ePermits.

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

Activities within this information collection are exclusive to APHIS's mission of preventing the importation, preparation, sale, or shipment of harmful veterinary biological products. The FDA has a related program where it regulates veterinary pharmaceuticals used for the treatment of diseases in animals which is different than the USDA APHIS program for regulating vaccines that aid in the prevention of diseases in animals. The two programs are complementary but do not overlap in their information collection activities.

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

APHIS estimates that 95 percent of the business respondents are considered small entities. Burden is minimized by requesting information that is typically maintained in electronic format, and efficient data collection and recordkeeping are routine elements of laboratory best practices.

**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.**

Failure to collect this information in a timely manner could result in harmful veterinary biologics being distributed or used in the United States. Consequently, injuries to animals or failure to prevent disease outbreaks would severely undermine consumer confidence in the effectiveness and safety of these products. Further, catastrophic damage could be inflicted upon U.S. livestock industries and pet populations, and bring great harm to the U.S. economy and 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.

The use of worthless, dangerous, or contaminated veterinary biologics could be catastrophic to the health of animals receiving them. Timeliness in identifying and stopping the distribution and sale of these products is crucial. Therefore licensees and permittees must send within 2 days stop distribution and sale notices to any jobbers, wholesalers, dealers, foreign consignees, or other persons known to have in their possession veterinary biological product subject to an APHIS stop distribution and sale action. The notices instruct the possessors 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. “Immediately” is defined as within 2 days and is commonly understood by APHIS and all affected licensees/permittees.

- **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:

Dr. Kent McClure
Animal Health Institute
1325 G Street NW, Suite 700
Washington, DC 20005
kmcclure@ahi.org

Joe O'Donnell
IDEXX Laboratories
1 IDEXX Drive
Westbrook, ME 04092
Joe-odennell@idexx.com

Dr. W. Ron DeHaven
American Veterinary Medical Association
1931 N. Meacham Road, Suite 100
Schaumburg, IL 60173
RDehaven@avma.org

On Monday, January 29, 2018, APHIS published in the Federal Register on pages 4024 and 4025 a 60-day notice seeking public comments on its plans to request a 3-year renewal of this collection of information. No comments from the public were received.

**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.**

Protection of confidential business information is done through Level 2 eAuthentication for all NCAH Portal users. Users only have access to information based on their user role designated on their APHIS Form 2007. The NCAH Portal is utilized for the transmission of information, not for the storage of information for the firm. All correspondence is deleted from the NCAH Portal 60 days after it has been completed.

No additional assurance of confidentiality is provided with this information collection. No information obtained in this collection shall 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 $4,548,466. APHIS arrived at this figure by multiplying the hours of estimated response time (122,998 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 $1,932,946.

**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 Approved |
|---|---|---|---|---|---|---|
| Annual Number of Responses | 298,820,801 | 0 | +298,781,131 | 0 | 0 | 39,670 |
| Annual Time Burden (Hours) | 122,998 | 0 | +44,616 | 0 | 0 | 78,382 |
| Annual Cost Burden ($) | 0 | 0 | 0 | 0 | 0 | 0 |

In this reinstatement request, the number of respondents increased from 202 to 10,183. The number of annual responses changed from 39,670 to 298,820,801 (an increase of 298,781,131), and the total burden hours changed from 78,382 to 122,998 (an increase of 44,616 hours). Most of the increases are attributed to a new labeling activity and the merger with 0579-0460 and 0209.

There are 50 activities and 42 have no change in their responses or burden hours, nor any changes due to agency estimate adjustments. There is a clerical error adjustment. The previous renewal request over-reported 169 responses and 167 burden hours.

The remaining 8 activities are program changes. Three reflect adjustments to activity response times. The first, Certificate of Licensing and Inspection (APHIS Form 2046 and 2047), changed its response time from .33 hours to .333 hours. The other two, Veterinary Biologics Production and Test Report, and Request for Reprocessing and Rebottling for a Serial or Subserial (both APHIS Forms 2008 and 2008A), had their response times increase from .73 hours to 1 hour. Two activities were merged from IC 0579-0460. The first added 800 responses and 40 hours of burden to a preexisting activity, Transmittal of Labels and Circulars or Outlines, Reporting (APHIS 2015). The other, Written Authorization Statement, Reporting, is new to the information collection and added

800 responses and 40 hours of burden. One activity, Adverse Event Report and Report Follow-up, was merged from 0579-0209 and added 15,999 responses and 31,998 hours of burden.

Finally, there are 2 new activities. CVB Inspection and Compliance Facility Document Submission Worksheet (APHIS Form 2009) refines a process and adds 1 response and 1 hour of burden. The other, and most significant change to this information collection request, is Package Labeling, a third party disclosure adding 298,763,700 responses and 8,365 hours of burden.

All of these changes with figures are presented in the following two tables.

**CHANGES IN RESPONSES**

| 9 CFR | ACTIVITY | RESP | PREVIOUS RESPONSES | NEW RESPONSES | DIFFERENCE | TYPE OF CHANGE |
|---|---|---|---|---|---|---|
| | Clerical error | | 39,670 | 39,501 | (169) | correction |
| 102.1 et al | APHIS Form 2009 | Bus | 0 | 1 | 1 | new |
| 112.1 | Package Labelling | Bus | 0 | 298,763,700 | 298,763,700 | new |
| 112.2 et al | APHIS Form 2015 | Bus | 4,000 | 4,800 | 800 | merger |
| 112.2 et al | Written Authorization | FG | 0 | 800 | 800 | merger |
| 116.9 | APHIS Form 2080, 2081 | Bus | 0 | 5,333 | 5,333 | merger |
| 116.9 | APHIS Form 2080, 2081 | FG | 0 | 5,333 | 5,333 | merger |
| 116.9 | APHIS Form 2080, 2081 | Indiv | 0 | 5,333 | 5,333 | merger |
| | | | 43,670 | + 298,824,801 | + 298,781,131 | |

**CHANGES IN BURDEN HOURS**

| 9 CFR | ACTIVITY | RESP | PREVIOUS BURDEN | NEW BURDEN | DIFFERENCE | TYPE OF CHANGE |
|---|---|---|---|---|---|---|
| | Clerical error | | 78,382 | 78,215 | (167) | correction |
| 102.1 et al | APHIS Form 2009 | Bus | 0 | 1 | 1 | new |
| 102.4 | APHIS Forms 2046, 2047 | Bus | 1,155 | 1,166 | 11 | response time |
| 112.1 | Package Labelling | Bus | 0 | 8,365 | 8,365 | new |
| 112.2 et al | APHIS Form 2015 | Bus | 200 | 240 | 40 | merger |
| 112.2 et al | Written Authorization | FG | 0 | 40 | 40 | merger |
| 113.5 et al | APHIS Form 2008, 2008A | Bus | 11,702 | 16,030 | 4,328 | response times |
| 116.9 | APHIS Form 2080, 2081 | Bus | 0 | 10,666 | 10,666 | merger |
| 116.9 | APHIS Form 2080, 2081 | FG | 0 | 10,666 | 10,666 | merger |
| 116.9 | APHIS Form 2080, 2081 | Indiv | 0 | 10,666 | 10,666 | merger |
| | | | 91,439 | + 136,015 | + 44,616 | |

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

A list of licensed establishments and licensed biological products, and a public annual report on the annual doses of biological products produced and destroyed, are published on the APHIS websites http://www.aphis.usda.gov/animal_health/vet_biologics/publications/CurrentProdCodeBook.pdf and https://www.aphis.usda.gov/animal_health/vet_biologics/publications/notice_84.pdf.

**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.