February 2022

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

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)

The APHIS Form 2009, Center for Veterinary Biologics (CVB) Inspection and Compliance Facility Document Submission Worksheet, supplements 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 Forms 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, APHIS may authorize a business 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. Manufacturers 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 Form 2001, plus storage location and shipping information. Permits for Research and Evaluation and Permits for Transit Shipment Only can be submitted to CVB via the NCAH Portal with an unverified identity eAuthentication account. Permits for General Sale and Distribution can be submitted to CVB via the NCAH Portal, but a verified identity eAuthentication account is required for this submission type.

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 by submitting a letter via the NCAH Portal.

State Notification of each Establishment and Product License Issued or Terminated
This activity is discontinued because it is no longer needed.

Package Labeling, (9 CFR 112.1, 9 CFR 112.2), (Business), (Third Party Disclosure)
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)
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)
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 with 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 112.2(e)(2)), (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 part 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.

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 APHIS Confirmatory Testing (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 submit 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 APHIS Confirmatory Testing (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 APHIS conducts confirmatory testing. Manufacturers 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

This activity is discontinued because it is no longer needed.

Request to Use an Isolate Beyond the Time Limit Prescribed, (9 CFR 113.113), (Business)

Under normal circumstances, microorganisms used to produce autogenous biologics may not be older than 24 months from the date of isolation, or 24 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) (Third Party Disclosure)
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. The National Centers for Animal Health (NCAH) Portal is an external-facing Web Portal that allows for electronic communications between external stakeholders and NCAH agencies, including the Center for Veterinary Biologics (CVB). CVB has guidance on how to use the NCAH Portal on the CVB website. This guidance includes User Guides and Training Videos.

- **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. Submitters use APHIS Form 2049 to correspond with the CVB Policy, Evaluation, and Licensing Unit. Submissions that can made using this form include protocols, reports, historical study summaries, post-license labels, outlines of production, special outlines, and other correspondence.

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 of the 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 (APHIS Form 2080); (9 CFR 116.9); (Businesses, Individuals, and States)
As part of CVB's pharmacovigilance program, manufacturers, veterinarians, and animal owners use APHIS Form 2080 to collect information required for 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. The form collects information on the purity, safety, potency, and effectiveness of licensed veterinary biologics distributed in the United States. Information collected includes submitter information, product information, detailed descriptions of events, suspected adverse event date(s), and reporter information.

Adverse Event Report Follow-Up (APHIS Form 2081)
This activity is discontinued because it is no longer needed.

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 a 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 the 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 the product.

Records of Antiserum or Serum Pasteurized, (9 CFR 113.450), (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 the product.

Identity of the Microorganism, (9 CFR 114.5), (Business)
Licensees must maintain a record of identity tests conducted on all microorganisms used to produce 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 the 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 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 112.5(e), 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; (4) the name of the licensee or subsidiary appearing on the label as the producer; and (5) translations of non-English labels and affirmation of those translations. These records must be kept for 2 years from the expiration date of the product.

Animal Records, (9 CFR 116.6; 9 CFR part 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 the 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) uses the National Centers for Animal Health (NCAH) Portal as a 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 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. CVB still accepts APHIS Form 2015 for all uses by firms not using the NCAH portal, either by choice or because they are prelicense firms that do not have access to the NCAH portal.

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

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

CVB allows submission of facility documents via the NCAH Portal by using APHIS Form 2048. CVB also allows electronic submissions of APHIS Forms 2017, 2046, 2046S, 2047, and 2047S for export certification. CVB will continue to process paper submissions for regulated entities. APHIS Form 2009 is a new form to use when submitting hard copy facility documents. It is a fillable PDF. Regulated industry entities that do not have access to the NCAH Portal will use the APHIS Form 2009.

APHIS Form 2005 is submitted electronically through the NCAH Portal.

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 NCAH Portal.

Paperwork and correspondence for patent term restoration, request for revision of the regulatory review period, the due diligence petition, applicant's response, and request for hearing is generally handled via hard copy.

In February 2021, CVB implemented mandatory reporting of adverse events by manufacturers, as set forth in 9 CFR 116.9. CVB and manufacturers use two forms of electronic reporting to facilitate this implementation. PV Express is available on the CVB website to report individual adverse event reports (AERs) and larger manufacturers that have the PV Works application can transmit an XML file to CVB. Adverse Event Reporting Guidance is provided on the CVB website.

CVB worked with manufacturers already using PV Works for reporting AERs to the Food and Drug Administration. The implementation of mandatory reporting of AERs significantly expands this information collection. There is specific guidance for the manufacturers on how to comply with the AER mandatory reporting on the CVB website.

CVB consulted the regulated industry of veterinary biological products and involved industry members in implementing electronic submissions to CVB. Regulated entities have complimented the process; the process has particularly facilitated work during the COVID-19 pandemic and has not resulted in any delays or negative impacts in the availability of effective veterinary biologics.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes 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 Food and Drug Administration has a related program that regulates veterinary pharmaceuticals used for the treatment of diseases in animals, which is different than the 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 3 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 3 days and is commonly understood as such by APHIS and all affected licensees/permittees.

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

  Currently, only the original is required. If a hard copy submission is used. Once the hard copy is received by the CVB, it is scanned, uploaded to CVB’s Licensing, Serial Release and Testing Information System (LSRTIS) database and routed for internal review electronically.

- **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. Discussed were how the Agency and the respondents obtain the necessary data and how frequently; how much data is available; the convenience and clarity of reporting formats and other collection instruments; and the clarity of, and necessity for, any recordkeeping requirements. The consulted individuals had no concerns with any of these items and had no further recommendations.

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On Wednesday, July 28, 2021, APHIS published in the Federal Register on pages 40446 and 40447 (see 86 FR 40446) 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 verified identity (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. APHIS uses the NCAH Portal to transmit information, not to store 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 $2,113,248. APHIS arrived at this figure by multiplying the hours of estimated response time (43,072 hours) by the estimated average hourly wage of the above respondents ($33.86) and then multiplying the result by 1.449 to capture benefit costs.

The average hourly rate was derived from the U.S. Department of Labor, Bureau of Labor Statistics May 2020 Report - Occupational Employment and Wages in the United States. (See http://www.bls.gov/news.release/pdf/ocwage.pdf: Importers and exporters [SOCC 41-4012, Sales Representatives, Wholesale and Manufacturing, Except Technical and Scientific Products, $35.34]; Shippers [SOCC 43-5071, Shipping, Receiving, and Inventory Clerks, $17.89]; State Animal Health Authorities [SOCC 29-1131, Veterinarians, $52.09]; Owners/Operators [SOCC 11-9013, Farmers, Ranchers, and Other Agricultural Managers, $36.93], and private individuals [SOCC 00-0000, $27.07].

According to DOL BLS news release USDL-21-0437 released March 18, 2021, employee benefits account for 31 percent of employee costs, and wages account for the remaining 69 percent. Mathematically, total costs can be calculated as a function of wages using a multiplier of 1.449.

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 $2,606,101.

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	435,797,533	0	**(14,624)**	136,991,356	0	298,820,801
Annual Time Burden (Hours)	43,072	0	**(88,605)**	**8,679**	0	122,998

In this renewal request, the number of respondents changed from 10,183 to 478. The number of annual responses changed from 298,820,801 to 435,797,533 (an increase of 136,976,732), and the total burden hours changed from 122,998 to 43,072 (a decrease of 79,926 hours).

There are 47 activities and 27 have no significant change in their responses or burden hours.

Items that changed significantly did so because of program and industry changes. No States issue or terminate veterinary biological products. Fluctuation in certificates of licensing and inspection occurred because of dip in domestic certificates but the regular cycle of foreign registration of veterinary biologics somewhat compensated. The third party labeling increased due to more “for further manufacture” licensed product being prepared. APHIS Form 2015 use decreased because it is only used by firms submitting hard copy and due to the increased use of the NCAH Portal by the regulated industry. The CVB is now receiving about 93 percent of its submissions electronically via the NCAH Portal.

The export market for licensed veterinary biologicals explains the increase in export-only labeling and the submission of APHIS Form 2017s, as this form certifies a specific serial of product being exported has been licensed and released for sale and distribution by the CVB. The reduction in requests to submit master seeds could be due to multiple factors, but the COVID-19 pandemic

likely caused a reduction in research and development of new novel veterinary biologics. There was a reduction in requests for extension of dating and this would indicate that the manufacturers didn't have surplus inventory that needed to be sold. VS Memorandum 800.69 changed the policy for autogenous products and allowed for all isolates to be used for 24 months without requesting authorization from the CVB and allowed distribution to nonadjacent herds without requesting authorization from the CVB, as long as the records were available at the firm for review during on-site inspections. There was a significant increase in the use of APHIS Forms 2048 and 2049 with the increased use of the NCAH Portal for CVB submissions.

In February 2021, the CVB implemented mandatory reporting of adverse reports, as per VS Memorandum 800.125, which affected the numbers for this action. Because of the implementation of the mandatory reporting requirement, the CVB was able to move from the previously estimated 9.999 respondents for the APHIS 2080 to a more accurately estimated number, 333 (a tenth of the original estimate). During the next information collection period in 2023, this number will see a significant increase. Mandatory reporting of adverse events can be submitted electronically by PV Express or PV Works or by using the fillable PDF form of APHIS Form 2080.

The 3 activities APHIS Form 2081, Request for Authorization to Prepare an Autogenous Biologic, and State Notification of each Establishment and Product License Issued or Terminated were discontinued. The respondents for these activities were correspondingly deleted.

Due to COVID-19, the CVB was not able to perform on-site inspections of the manufacturers that normally would have happened to appraise test, label, and seed records recordkeeping. There was an initiative to start performing virtual records inspections, but that process wasn't initiated until early 2021.

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

CHANGES IN RESPONSES

9 CFR	ACTIVITY	RESPONDENT	CURRENT RESPONSES	PREVIOUS RESPONSES	CHANGE	TYPE OF CHANGE
	Rqst for Authorization to Prepare	Bus	0	20	(20)	discontinue
	State Notification License	State	0	1	(1)	discontinue
	APHIS 2081	Bus, State, Indiv	0	6,000	(6,000)	discontinue
102.1, 108.2	APHIS Form 2001	Bus	22	20	2	estimate
102.1 et al	APHIS Form 2009	Bus	46	1	45	estimate
102.1	APHIS Form 2003	Bus	88	75	13	estimate
102.4	APHIS 2046, 2047	Bus	1,240	3,500	(2,260)	estimate
102.4, 114.7	APHIS Form 2007	Bus	1,170	720	450	estimate
102.6	Petition for Reissue	Bus	24	10	14	estimate
103.1	Application to Produce	Bus	112	50	62	estimate
103.3	App for Authorization	Bus	315	360	(45)	estimate
104.5	APHIS Form 2005	Bus	540	220	320	estimate
105.4	Show Intent/Production	Bus	9	50	(41)	estimate

9 CFR	ACTIVITY	RESPONDENT	CURRENT RESPONSES	PREVIOUS RESPONSES	CHANGE	TYPE OF CHANGE
112.1	Package Labelling	Bus	435,749,193	298,763,700	136,985,493	estimate
112.2 et al	APHIS Form 2015	Bus	156	4,800	(4,644)	estimate
112.2 et al	Written Authorization	FG	2,475	800	1,675	estimate
112.5	List of Approved Labels	Bus	83	48	35	estimate
112.47 et al	APHIS Form 2017	Bus	1,860	1,000	860	estimate
113 et al.	APHIS Form 2018	Bus	352	400	(48)	estimate
113.3	APHIS Form 2020	Bus	13,500	11,500	2,000	discretionary
113.3, 113.6	APHIS 2072	Bus	32	48	(16)	estimate
114.18	APHIS 2008&2008A	Bus	16,312	16,030	282	estimate
113.52 et al	APHIS 2070	Bus	14	120	(106)	estimate
114.14	Request for Extension	Bus	33	500	(467)	estimate
115.2	Wholesaler Notifications	Bus	1	5	(4)	discretionary
115.2(b)(3)	Inventory/Lic/Permittees	Bus	1	5	(4)	discretionary
115.2(b)(4)	Accounting of Inventory	Bus	1	50	(49)	estimate
116.5	APHIS Form 2048	Bus	900	25	875	estimate
116.5	APHIS Form 2049	Bus	6,930	25	6,905	estimate
116.9	APHIS Form 2080	Bus	11	3,333	(3,322)	discretionary
116.9	APHIS Form 2080	State	1	3,333	(3,332)	discretionary
116.9	APHIS Form 2080	Indiv	332	3,333	(3,001)	discretionary
109.2	Steriliz./Pasteur. Records	Bus	61	100	(39)	discretionary
113.5, 113.6	Records of All Tests	Bus	88	100	(12)	discretionary
113.45	Records/Serum/Pasteur.	Bus	1,172	20	1,152	discretionary
114.5	Records/Microorg. Used	Bus	95	100	(5)	discretionary
114.6 et al.	Records of Production	Bus	88	100	(12)	discretionary
112.2 et al	Label Records	Bus	88	100	(12)	discretionary
116.6, 117	Animal Records	Bus	88	100	(12)	discretionary
			435,797,433	298,820,702	136,976,731	

CHANGES IN BURDEN HOURS

9 CFR	ACTIVITY	RESPONDENT	CURRENT BURDEN	PREVIOUS BURDEN	CHANGE	TYPE OF CHANGE
	Rqst for Auth to Prepare		0	5	(5)	discontinue
	State Notification License		0	1	(1)	discontinue
	APHIS 2081		0	12,000	(12,000)	discontinue
102.1, 108.2	APHIS Form 2001	Bus	22	20	2	estimate
102.1 et al	APHIS Form 2009	Bus	7	1	6	estimate
102.1	APHIS Form 2003	Bus	88	75	13	estimate
102.4	APHIS 2046, 2047	Bus	413	1,166	(753)	estimate

9 CFR	ACTIVITY	RESPONDENT	CURRENT BURDEN	PREVIOUS BURDEN	CHANGE	TYPE OF CHANGE
102.4, 114.7	APHIS Form 2007	Bus	234	144	90	estimate
102.6	Petition for Reissue	Bus	24	10	14	estimate
103.1	Application to Produce	Bus	56	25	31	estimate
103.3	APHIS Form 2071	Bus	315	360	(45)	estimate
104.5	APHIS Form 2005	Bus	540	220	320	estimate
105.4	Show Intent/Production	Bus	9	50	(41)	estimate
112.1	Package Labelling	Bus	12,201	8,365	3,836	estimate
112.2 et al	APHIS Form 2015	Bus	8	240	(232)	estimate
112.2 et al	Written Authorization	FG	124	40	84	estimate
112.5	List of Approved Labels	Bus	21	12	9	estimate
112.47 et al	APHIS Form 2017	Bus	1,860	1,000	860	estimate
113 et al.	APHIS Form 2018	Bus	36	40	(4)	estimate
113.3	APHIS Form 2020	Bus	4,455	3,450	1,005	discretionary
113.3, 113.6	APHIS 2072	Bus	32	48	(16)	estimate
114.18	APHIS 2008&2008A	Bus	16,312	16,030	282	estimate
113.52 et al	APHIS 2070	Bus	14	120	(106)	estimate
114.14	Request for Extension	Bus	33	500	(467)	estimate
115.2	Wholesaler Notifications	Bus	1	1	0	discretionary
115.2(b)(3)	Inventory/Lic/Permittees	Bus	2	5	(3)	discretionary
115.2(b)(4)	Accounting of Inventory	Bus	2	100	(98)	estimate
116.5	APHIS Form 2048	Bus	450	13	437	estimate
116.5	APHIS Form 2049	Bus	3,465	13	3,452	estimate
116.9	APHIS Form 2080	Bus	4	6,666	(6,662)	discretionary
116.9	APHIS Form 2080	State	1	6,666	(6,665)	discretionary
116.9	APHIS Form 2080	Indiv	110	6,666	(6,556)	discretionary
109.2	Steriliz./Pasteur. Records	Bus	244	950	(706)	discretionary
113.5, 113.6	Records of All Tests	Bus	176	17,200	(17,024)	discretionary
113.45	Records/Serum/Pasteur.	Bus	586	920	(334)	discretionary
114.5	Records/Microorg. Used	Bus	475	14,300	(13,825)	discretionary
114.6 et al.	Records of Production	Bus	264	525	(261)	discretionary
112.2 et al	Label Records	Bus	264	25,000	(24,736)	discretionary
116.6, 117	Animal Records	Bus	176	3	173	discretionary
			43,024	122,950	(79,926)	

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_88.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.

The OMB approval expiration date will be displayed.

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.