2011 SUPPORTING STATEMENT – 0579-0013
VIRUS-SERUM-TOXIN ACT AND REGULATIONS

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 (37 Stat. 832-833, 21 USC 151-159) gives the United States Department of Agriculture (USDA) the authority to promulgate regulations designed to prevent the importation, preparation, sale, or shipment of harmful veterinary biological products. These regulations are contained in Title 9, Code of Federal Regulations, Subchapter E, Parts 102 to 124.

A veterinary biological product is defined as all viruses, serums, toxins, and analogous products of natural or synthetic origin (such as vaccines, antitoxins, or the immunizing components of microorganisms intended for the diagnosis, treatment, or prevention of diseases in domestic animals).

To fulfill its mission of preventing the importation, preparation, sale, or shipment of harmful veterinary biological products, the Policy, Evaluation, and Licensing Unit of the Center for Veterinary Biologics (CVB), Veterinary Services, Animal and Plant Health Inspection Service (APHIS), USDA, issues licenses to qualified establishments that produce veterinary biological products, and issues permits to importers seeking to import such products into the United States. APHIS also enforces regulations concerning production, packaging, labeling, and shipping of veterinary biological products, and sets standards for the testing of these products.

The purpose of these regulations is to ensure that veterinary biological products used in the U.S. are not worthless, contaminated, dangerous, or harmful.

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

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

2. Indicate how, by whom, how frequently, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

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

Application for US Veterinary Biologics Establishment License (includes plot plans and blueprints) (APHIS Form 2001)
The prospective owner/operator (whether a corporation, partnership, or individual) of a veterinary biologics establishment uses APHIS Form 2001 to apply for a United States Veterinary Biologics Establishment License. Such establishments must meet minimum standards for facilities and production methods. The information collected on Form 2001 allows APHIS to determine that the conditions of the facilities and the method of preparation of the product are likely to accomplish the intended purpose.

Application for US Veterinary Biologics License (APHIS Form 2003)
The establishment owner/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.

Qualifications of Veterinary Biologics Personnel (APHIS Form 2007)
APHIS' regulations require that licensed establishments be operated under direct supervision of a person competent by education and experience to handle all matters pertaining to the preparation and testing of veterinary biological products. Data on this form, which is completed by the establishment's owner/operator, provides APHIS with a biographical summary of each designated person responsible for any phase of preparation of a biological product.

Transmittal of Labels and Circulars or Outlines (APHIS Form 2015)
APHIS' regulations require that labels used with veterinary biological products prepared at licensed establishments or imported for general distribution or sale must be reviewed, by APHIS, for compliance with USDA regulations and approved in writing prior to use. Our regulations also stipulate that an "Outline of Production" must be on file with APHIS for each licensed product or for each biological product authorized to be imported into the United States for distribution and sale. APHIS Form 2015 provides the manufacturer of the product, or the importer of the product, with an orderly and standardized method for transmitting this information to us.

Official Export Certificate for animal Biological Products (APHIS Form 2017)
Some foreign countries require U.S. exports to be accompanied by an Official Export Certificate for Animal Biological Products. This form provides official certification by APHIS that the products have been produced and tested in approved, inspected facilities according to specific manufacturing standards, and are therefore safe. APHIS Form 2017 is the form used by the U.S. exporter to request this certification from APHIS.

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

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

- **The Reply Section** of the form is completed by CVB personnel and it 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 who is processing the form, and the official's signature.

- **The Receipt Section** of the form is completed by the individual who receives the shipment (usually the individual who requested the shipment) and asks for the number of containers, the condition of the shipment, the date received, the name and title of the individual who received the shipment, and that individual's signature.

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

Applications for US Veterinary Biologics Product Permit (APHIS Form 2005)
APHIS is authorized to issue three types of permits for importing veterinary biological products. They are (1) a Biological Product Permit for Research and Evaluation, (2) a Biological Product Permit for Distribution and Sale, and (3) a Biological Permit for Transit Shipment Only. The APHIS Form 2005 is the application that the importer completes and submits to APHIS to apply for any one of these permits.

Shipment and Receipt of Biologics Samples (APHIS Form 2020)
APHIS regulations require that manufacturers or importers must furnish APHIS with samples of serials and sub-serials of a biological product manufactured in the United States or imported into the United States. APHIS Form 2020, which is completed by the manufacturer or importer, ensures that each submission of samples to an APHIS laboratory includes the information necessary for APHIS to conduct the appropriate tests, and that the samples have been selected in accordance with APHIS regulations.

Veterinary Biologics Production and Test Report (APHIS Form 2008 and Form 2008A)
No serial or sub-serial of a biological product is eligible for release for distribution and sale prior to the completion of tests prescribed by APHIS regulations. The APHIS Forms 2008 and 2008A are completed and submitted by the manufacturer to document the completion of all required tests. This form must be submitted to APHIS before the release of the serial or sub-serial.

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

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

APHIS Forms 2046, 2046S, 2047, and 2047S make it easier for manufacturers to apply to APHIS for such certificates.

List of Licensed Biological Products
When APHIS requests a list of licensed products to be continued in production at a licensed establishment, the licensee must supplement the list with information for each product. This information must include the date each product's production outline was last revised and filed with APHIS.

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

Petition for Reissue of Conditional License
In order 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. Prior to termination of the license, the licensee may request reissuance. These requests must be substantiated with data and information obtained since the license was issued.

Application to Produce Experimental Products
APHIS may authorize the preparation of experimental products on the premises of a licensed establishment if it is determined that such preparation will not result in the contamination of 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.

Request for Authorization to Ship Unlicensed Biological Products for Experimental Field Studies in the United States
For the benefit of license applicants and to permit and encourage research, a business may be authorized by APHIS to ship unlicensed biological products (to locations within the United States) 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.

The following activities are required in order to complete the request for authorization to ship unlicensed biological products for experimental field studies in the United States. The following requirements are collectively captured in this collection under the "Request for authorization to ship unlicensed biological products for experimental field studies in the U.S." A request for authorization to ship an unlicensed biological product for experimental study and evaluation must be accompanied by (a) one copy of a permit or letter of permission from the appropriate State or foreign animal health authorities, (b) two copies of a tentative list of the names of the proposed recipients and quantity of experimental product that is to be shipped to each individual, (c) two copies of a description of the product, recommendations for use, and results of preliminary research work; (d) three copies of labels or label sketches which show the name or identification of the product and which bear the statement,

Notice –For Experimental Use Only—Not For Sale; (e) two copies of a proposed general plan covering the methods and procedures for evaluating the product and for maintaining records of the quantities of experimental product prepared, shipped, and used, (f) data acceptable to APHIS demonstrating that the use of the experimental biological product in meat animals is not likely to result in the presence of any unwholesome condition in the edible parts of animals subsequently presented for slaughter, (g) a statement from the research investigator or research sponsor agreeing to furnish (if requested by APHIS) additional information concerning each group of meat animals involved prior to movement of these animals from the premises where the test is to be conducted, and (h) any information APHIS may require to assess the product's impact on the environment.

Show Intent to Resume Production

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

State Notifies APHIS of each Establishment and Product License Issued or Terminated

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

List of Approved Labels Currently Being Used

When a request is received from APHIS, a licensee or permittee must submit to APHIS a list of all approved product labels currently being used. Each label listed must be identified as to (1) the name and product code number as it appears on the product license or permit for the product, (2) where applicable, the size of the package (doses, ml., cc., or units) on which the label will be used, (3) the label number and date assigned, and (4) the name of the licensee or subsidiary appearing on the label as the producer.

Request for Authorization to Prepare an Autogenous Biologic for Use in Herds Adjacent to the Herd of Origin

Under normal circumstances, microorganisms from one herd must not be used to prepare an autogenous biologic for another herd. APHIS, however, may authorize preparation of an autogenous biologic for use in herds adjacent to the herd of origin when adjacent herds are considered to be at risk. To request authorization to prepare a product for use in herds adjacent to the herd of origin, the establishment seeking authorization must submit in writing, to the Director, CVB, Inspection and Compliance (IC), the following information: (1) the name, address, and phone number of the owner of the herd of origin; (2) the attending veterinarian's name, address, and phone number; (3) the species and number of animals in the herd of origin, (4) identification of the microorganisms, at least to genus; (5) the diagnosis or clinical signs of the disease observed, (6) the name and address of the person who isolated the microorganisms and the date of isolation, (7) the number of doses of autogenous biologic requested and vaccination schedule, (8) each adjacent herd owner's name, address, and phone number; (9) the number and species of animals in each adjacent herd, and (10) the attending veterinarian's or approved specialist's assessment of the involvement of the adjacent herds with the disease observed. The applicant must also notify the State Veterinarian or other appropriate State official when an autogenous biologic is to be used in adjacent herds.

Request to Use an Isolate Beyond the Time Limit Prescribed
Under normal circumstances, microorganisms used for the production of autogenous biologics may not be older than 15 months from the date of isolation, or 12 months from the date of harvest of the first serial of product produced from the microorganisms, whichever comes first. APHIS, however, may authorize production of additional serials from microorganisms older than the above stated time periods, provided that the business submits in writing, certain information to the Director, CVB-IC, including: (1) the attending veterinarian's or approved specialist's current assessment of the continued involvement of a herd with the originally isolated microorganisms, including a summary of the diagnostic work that has been done to support 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 that APHIS may require in order to determine the need to use the microorganism to make additional serials.

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

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

Reports on Activities
When required by APHIS, the licensee, permittee, or foreign manufacturer (whose products are being offered for importation) must prepare and submit written reports containing accurate and complete information concerning biological products (including but not limited to product development and preparation, as well as market suspensions and recalls) to the Director, CVB-PEL. In addition, these public must also provide copies of these documents in the following situations:

- **Request for Authorization to Ship Unlicensed Biological Products for Experimental Field Studies in Foreign Countries**
  Individuals wishing to ship unlicensed biological products to foreign countries for the purpose of evaluating such experimental products must, in addition to submitting the above information to APHIS, submit identical information 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.

- **Submit Summary of Field Studies**

Applicants, who request authorization from APHIS to ship unlicensed biological products for experimental field studies in the United States must, upon conclusion of the field studies, summarize and submit the results of the studies to APHIS.

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

Licensees and permittees must submit requests for extension of the term of a veterinary biologic patent to the Patent and Trademark Office of the U.S. Department of Commerce; APHIS will assist that office in determining whether a patent related to a biological product is eligible for a patent term extension.

Request for Revision of the Regulatory Review Period

Not later than 30 days after receiving a letter of application for extending the term of a veterinary biologic patent from the Patent and Trademark Office, APHIS will determine the regulatory review period for the product. Any interested person may request a revision of the regulatory review period determination within the 30 day period beginning on its publication date in the Federal Register. This request must be submitted in writing, to the Director, CVB-PEL, 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 documentary evidence.

Due Diligence Petition and Certification Statement of True and Completed Copy

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

Applicants Response to Petition

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

Request for Due Diligence Hearing

Any interested person may request, within 60 days beginning on the date of publication of a due diligence determination, that APHIS conduct an informal hearing on the due diligence determination. The request for a hearing must be submitted to APHIS, and must contain (1) the docket number of the Federal Register notice of APHIS's regulatory review period determination, (2) a full statement of the facts upon which the request for hearing is based, (3) the name, the address, and the 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 upon the petitioner of the due diligence determination and the applicant for patent term extension by certified or registered mail or by personal service.

RECORDKEEPING

Records of Disposition of Test Animals

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

Records of Exempt Biologics

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

Sterilization and Pasteurization Records

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

Records of Antiserum or Serum Pasteurized

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

Records of All Tests

No biological product can be released prior to the completion of tests designed to establish that the product is pure, safe, potent, and efficacious. Records of all tests must be maintained, and test results must be submitted by the business to APHIS. Detailed records of all tests conducted on each serial and subserial must also be maintained by the licensee. Summaries of these tests must be submitted to APHIS prior to the release of the serial or subserial. These records must be kept for 2 years from the expiration date of an experimental product.

Animal Records

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

Identity of the Mircoorganism, Recordkeeping

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

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

Records of Production of Product, Inventory and Disposition
Each licensee, permittee, and foreign manufacturer of biological products imported into the United States must maintain, at the licensed or foreign establishment in which the products are prepared, detailed records of information necessary to give a complete accounting of all the 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 be detailed as necessary for a clear understanding of each step by 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, and they must be retained for a period of 2 years after the expiration date of the product.

Label Records
Each licensee and permittee must maintain a list of all approved labels currently being used. The inventory records must account for all labels printed including the disposition of those not used in labeling a product, and should be kept current for the entire period that a product remains in production. These records must be kept for 2 years from the expiration date of an experimental product. Each label must be identified as to (1) the name and product code number as it appears on the product license or permit for the product, (2) where applicable, the size of the package (does, ml, cc, or units) on which the label will be used, (3) the label number and date assigned, and (4) the name of the licensee or subsidiary appearing on the label as the producer.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

Currently, only the APHIS Form 2005 can be submitted online whereas APHIS Forms 2001, 2003, 2007, 2008, 2008A, 2017, 2018, 2046, 2046S, 2047, 2047S and 2020 are available at www.aphis.usda.gov/animal_health/vet_biologics/vb_forms.shtml and can be printed, completed, and mailed to APHIS. This submission must be done via mail due to inclusion of personally identifiable and confidential business information located on the forms. To maintain the integrity of the forms and because APHIS does not yet have the means to obtain an electronic signature from the public, these forms must be mailed to APHIS.

The APHIS Form 2015 cannot be placed online. It is a multi-copy, tear-away form that is unsuitable for downloading.
All other information collection activities that do not involve official forms (for example, a request for extending the expiration date for a serial or subserial, a request for a revision of a regulatory review period, or a request for a due diligence hearing) can be accomplished with an email or phone call to APHIS. Any requested documentation such as protocols, reports, field study summaries, copies of permits or label sketches, research material, product descriptions, or other material can also be emailed to APHIS.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purpose described in item 2 above.

The information that APHIS collects in connection with this program is exclusive to its mission of preventing the importation, preparation, sale, or shipment of harmful veterinary biological products. It should be noted that the Food and Drug Administration (FDA) regulates veterinary pharmaceuticals (drugs used for the treatment of disease in animals), while APHIS regulates an entirely different category of products (vaccines) that aid in the prevention of disease in animals through stimulation of the immune system. APHIS and FDA, therefore, have distinct and separate regulatory missions that do not result in overlapping information collection activities.

It must also be noted that California has its own veterinary biologics regulatory program. However, California only regulates products produced and distributed solely within its boundaries. USDA licensed products do not require a California license to be distributed in California.

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

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

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

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

7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with the general information collection guidelines in 5 CFR 1320.5.

- **requiring respondents to report information to the agency more often than quarterly;**
- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
- **requiring respondents to submit more than an original and two copies of any document;**
- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;**
- **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**
- **requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

This information collection is conducted in a manner consistent with the guidelines established 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.

In 2011, APHIS engaged in productive consultations with the following individuals concerning the information collection activities associated with this program:

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On Friday, June 24, 2011, pages 37057 -37058, APHIS published in the Federal Register, a 60- day notice seeking public comments on APHIS' plans to request a 3-year extension of this collection of information. During that time APHIS received one comment from Jeffery M Zinza, Life Technologies Corporation, giving background information about his company and providing ideas on how the processes APHIS uses to approve Veterinary Biologics Licenses can be streamlined.

9. Explain any decision to provide any payment or gift to respondents, other than reenumeration of contractors or grantees.

This information collection activity involves no payments or gifts to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

No additional assurance of confidentiality is provided with this information collection. Any and all information obtained in this collection shall not be disclosed except in accordance with 5 U.S.C.552a.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior or attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

This information collection activity will ask no questions of a personal or sensitive nature.

12. Provide estimates of the hour burden of the collection of information. Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated.

•Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. If this request for approval covers more than one

form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB Form 83-I.

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

•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 $2,309,685.30. APHIS arrived at this figure by multiplying the hours of estimated response time (74,386 hours) by the estimated average hourly wage of the above respondents ($31.05).

Importers and exporters $29.55 [41-4012 Sales Representatives, Wholesale and Manufacturing, Except Technical and Scientific Products]
Shippers $14.03 per hour [43-5071 Shipping, Receiving, and Traffic Clerks]
State Animal Health Authorities: $31.13 [11-9011 Farm, Ranch, and Other Agricultural Managers]
Owners/Operators: $49.47 [11-0000 Management Occupations]

The average hourly rate is derived from the U.S. Department of Labor; Bureau of Labor Statistics May 2009 Report – National Occupational Employment and Wage Estimates United States. See http://www.bls.gov/oes/#tables

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.

There is zero annual cost burden associated with capital and start-up costs, operation and maintenance expenditures, and purchase of services.

14. Provide estimates of annualized cost to the Federal government. Provide a description of the method used to estimate cost and any other expense that would not have been incurred without this collection of information.

The annualized cost to the Federal Government is estimated at $451,034.26. (See APHIS Form 79.)

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

ICR Summary of Burden:

	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	19,304	0	-28	-2,394	0	21,726
Annual Time Burden (Hr)	74,386	0	-13	-6,538	0	80,937
Annual Cost Burden ($)	0	0	0	0	0	0

In the previous information collection there were 500 total respondents and in the current collection there are 202 total respondents; a decrease of -298 total respondents from the previous collection due to fewer requests for licenses.

The Autogenous Biologics Labels were deleted from the collection causing a program change decrease of -30 respondents and -30 responses resulting in a decrease of -15 burden hours. However, with the addition of the Individual IC (Due diligence petition and certification statement of true and completed copy and Request for restriction on distribution and use of veterinary biological product) there is a program change increase of +1 respondent and +2 responses with an increase of +2 burden hours. The total program change is -29 respondents, -28 responses and -13 hours.

With fewer request for licenses there were adjustments to both the State and business ICs. There is an adjustment to the State IC with a decrease of -42 responses and -1 burden hour. Under the Business IC there was an adjustment of -2,352 responses and -6,537 burden hours to the various recordkeeping responses. The total adjustment is -2,394 responses and -6,538 total burden hours.

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

APHIS has no plans to publish information it collects in connection with this program.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

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

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

APHIS can certify compliance with all provisions under the Act.

B. Collections of Information Employing Statistical Methods

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