Supporting Statement-OMB No. 0579-0090
Specimen Submission

September 30, 2009

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 Animal Health Protection Act (AHPA) of 2002 is the primary Federal law governing the protection of animal health. The law gives the Secretary of Agriculture broad authority to detect, control, or eradicate pests or diseases of livestock or poultry. The Secretary may also prohibit or restrict import or export of any animal or related material if necessary to prevent the spread of any livestock or poultry pest or disease. The AHPA is contained in Title X, Subtitle E, Sections 10401-18 of P.L. 107-171, May 13, 2002, the Farm Security and Rural Investment Act of 2002.

Disease prevention is the most effective method for maintaining a healthy animal population and for enhancing the United States' ability to globally compete in the trade of animals and animal products. Animal disease prevention cannot be accomplished without the existence of an effective disease surveillance program; an activity that is carried out by the U.S. Department of Agriculture, Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS). VS Forms 10-4 and 10-4A are critical components of APHIS' disease surveillance mission. They are used routinely when specimens (such as blood, milk, tissue, or urine) from any animal (including cattle, swine, sheep, goats, horses, and poultry) are submitted to APHIS' National Veterinary Services Laboratories (NVSL) for disease testing.

The foundation of the National Tick Surveillance Program is based on the information submitted on VS Form 5-38, in addition to critical surveillance information needed for the Cattle Fever Tick Eradication Program. This information identifies the individual submitting the tick samples.

APHIS is asking OMB to approve its use of this information collection activity 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.

VS Form10-4, Specimen Submission
VS Form I0-4A, Continuation Sheet for Specimen Submission

VS Forms 10-4 and 10-4A are completed by State veterinarians or other State representatives, accredited veterinarians, private laboratories, and research institutions. Authorized individuals complete the form using information obtained through discussions with the animal owners.

The animal disease surveillance program is based on the information submitted on VS Forms 10-4 and 10-4A. This information identifies the individual animal from which specimens were taken, the animal's herd or flock, the type of specimen submitted, and the purpose for submitting the specimen. Without the information contained on this form, NVSL staff would not be able to identify or process the specimens sent for analysis. Additionally, if the information is not collected (or collected less frequently), APHIS would not have the critical information necessary to effectively operate a disease surveillance program.

VS Form 5-38, Parasite Submission Form

VS Form 5-38 is completed by State veterinarians or other State representatives, accredited veterinarians, private laboratories, research institutions, and individuals/households.

The National Tick Surveillance Program is based on the information submitted on VS Form 5-38, in addition to critical surveillance information needed for the Cattle Fever Tick Eradication Program. This information identifies the individual submitting the tick samples.

The information on tick species determination is critical to personnel with the APHIS National Center for Import and Export (at the U.S. Border Ports) and the APHIS Cattle Fever Tick Eradication Program, who are responsible for surveillance and eradication of cattle fever ticks (*Boophilus* spp.). If the information is not collected (or collected less frequently), APHIS would not have the critical tick species information necessary to effectively operate a surveillance and eradication program for cattle fever ticks.

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 NVSL Laboratory Information Management System (LIMS) currently requires submission of specimens with hard copies of VS forms 10-4 and 10-4A to ensure proper identification of the samples; therefore, the forms currently cannot be transmitted electronically. A new LIMS is in development that is expected to provide the capabilities necessary to support submission of data from VS Forms 10-4 and 10-4A; however, evaluations of electronic capability and funding for the database system will not be determined until fiscal year 2010.

VS Form 5-38 must be an original copy and is therefore not available electronically.

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 is not available from any other source. APHIS is the only Federal Agency responsible for preventing, detecting, controlling, and eradicating animal diseases from the United States.

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

The information collected from small businesses (approximately 25 percent) is the absolute minimum needed to operate a national disease surveillance program.

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.

The animal disease surveillance program is based on the information submitted on VS Forms 10-4, 10-4A and VS Form 5-38. If the information is not collected (or collected less frequently), APHIS would not have the critical information necessary to effectively operate a disease surveillance program. No purpose would be served by submitting a specimen for laboratory analysis that is not accompanied by the appropriate documentation to identify the animals and herds from which the specimens were taken.

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

This information collection is conducted in a manner consistent with the guidelines established in 5 CFR1320.5.

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 record keeping, 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 2009, APHIS engaged in productive consultations with the following individuals in connection with the information collection activities:

Gene Erickson
North Carolina Department of Agriculture and Consumer Services
Rollins Animal Disease Diagnostic Laboratory
2101 Blue Ridge Road
Raleigh, NC 27607
(919) 733-3987

Gary Anderson
Kansas State University
2 Fairchild Hall
Manhattan, KS 66506
(785) 532-4454

Betty Miguel
New Jersey Department of Agriculture
John Fitch Plaza
Trenton, NJ 08625-0330
(609) 292-3965

On Monday, April 6, 2009, pages 15432-15433, APHIS published in the Federal Register, a 60-day notice seeking public comments on its plans to request a 3-year renewal of this collection of information. 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.

No additional assurance of confidentiality is provided with this information collection. However, the confidentiality of information is protected under 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 he made of the information, the explanation to he 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 83-1**.

See APHIS Form 71. Burden estimates were developed from discussions with accredited veterinarians, State veterinarians, and other personnel who are qualified to submit specimens for laboratory analysis; as well as herd owners who provide the information necessary for completing the VS Form10-4, 10-4A and VS Form 5-38.

- **Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories.**

Respondents are animal owners, State veterinarians or other State representatives, accredited veterinarians, private laboratories, and research institutions. APHIS estimated the total annualized cost to these respondents to be $257,050.49. APHIS arrived at this figure by multiplying the hours of estimated response time (9266.42 hours) by the estimated average hourly wage of the above respondents ($27.74). This hourly rate was derived from the U.S. Department of Labor; Bureau of Labor Statistics May 2008 Report - Occupational Employment and Wages in the United States. See http://www.bls.gov/oes/.

13. Provide estimates of the total annual cost burden to respondents or record keepers resulting from the collection of information (do not include the cost of any hour burden shown in items 12 and14). 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 $190,838. (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.

There is an adjustment of 2,199 hours because the estimated response time was recalculated to more accurately reflect the time to complete forms VS 10-4 and 10-4A.

There is also a program change of +100 total annual responses, and an additional 68 total burden hours because of the addition of VS Form 5-38, Parasite Submission Form, which inadvertently was not included in previous submissions.

The number of respondents dropped from 14,000 to 3,208 because the number of laboratories and research institutions submitting specimens to the APHIS National Veterinary Services Laboratories for disease testing decreased. However, the laboratories now are submitting specimens ten times per year instead of two as previously reported in the last submission.

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 collected 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.

These forms are used in two other information collections; therefore, it is not practical to include an OMB expiration date because of the different expiration dates for each collection. APHIS is seeking approval to not display the OMB expiration date on these forms.

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

APHIS can certify compliance with all provisions.

B. Collections of Information Employing Statistical Methods

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