SUPPORTING STATEMENT OMB NO. 0579-0232 STANDARDS FOR PRIVATELY OWNED QUARANTINE FACILITIES FOR RUMINANTS

May 21, 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 animals.

Title 21, U.S.C. authorizes sections 111, 114, 114a, 114-1, 115, 120, 121, 125, 126, 134a, 134c, 134f, and 134g of 21 U.S.C. These authorities permit the Secretary to prevent, control and eliminate domestic diseases such as tuberculosis, as well as to take actions to prevent and to manage exotic diseases such as foot-and-mouth disease (FMD) and other foreign diseases. Disease prevention is the most effective method for maintaining a healthy animal population and enhancing our ability to compete in exporting animals and animal products.

In connection with this mission, the Veterinary Services Division of USDA's Animal and Plant Health Inspection Service (APHIS) enforces regulations that pertain to the importation of animals and animal products in the United States and the prevention of foreign animal disease incursions into the United States. These regulations are contained in Title 9, Chapter I, Subchapter D, and Parts 91 through 99 of the Code of Federal Regulations.

These standards triggered a number of information collection activities when applicants apply for approval to establish and operate privately owned quarantine facilities. These information collections include the writing of application letters, the maintenance of daily logs, and the writing of variance requests.

APHIS is asking OMB to approve, for 3 years, its use of this information collection in connection with its efforts to create a system whereby private individuals can operate (with APHIS oversight) their own facilities for the quarantine of imported ruminants.

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.

Application letter

Anyone desiring to obtain APHIS approval to establish and operate a private quarantine facility for ruminants must submit in writing to APHIS a letter that contains the full name and mailing address of the applicant, the location and street address of the proposed facility, a description of the financial resources for construction, operation, and maintenance of the facility; the anticipated origin of the ruminants to be quarantined, and the expected size and frequency of shipments. In addition to the letter, the applicant must provide APHIS with blueprints of the proposed facility and all approved State and local permits for construction and operation of such a facility. This information can be submitted to APHIS via fax, postal mail, or email. APHIS uses this information to determine whether an applicant is capable of designing, equipping, operating, and maintaining a quarantine facility that meets APHIS standards for biological security. Based on this information, APHIS will determine if permission will be granted to establish and operate a private quarantine facility for ruminants.

Compliance Agreement

This is a signature only document in which the applicant agrees to establish, operate, and maintain the private quarantine facility in accordance with APHIS standards and requirements. The cooperative agreement further stipulates that the operator is responsible for the cost of building the facility, as well as any costs associated with its maintenance and operation.

Daily Log

For purposes of security, facility operators must maintain a daily log to record the entry and exit of all persons entering and leaving the facility while quarantine is in progress. These logs must be made available to an APHIS representative upon request, and must be kept for 2 years following the release of the ruminants from quarantine.

Request for Variance

Facility operators desiring a variance from APHIS regulatory standards must submit their variance request, in writing, to APHIS at least 30 days in advance of the arrival of ruminants at the quarantine facility. APHIS will grant a variance to existing facility requirements relating to location, construction, design, sanitation, security, operating procedures, recordkeeping, or other provisions if we determine that there is no detrimental effect on the health of the ruminants or to the overall biological security of the quarantine operation.

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 major information collection components of this program, including the application letter, and variance request can be submitted to APHIS electronically by email as scanned documents. The information regarding the application letter will be available through the NCIE at 301-734-8364; by fax at 301-734-6402. Guidelines for submitting an application will be available by the end of 2009, on the APHIS homepage at www.aphis.usda.gov.

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 foreign animal diseases from entering 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 is the absolute minimum needed to ensure that privately owned quarantine facilities for ruminants are being operated according to APHIS standards for Biosecurity.

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.

If the information was collected less frequently or not collected, APHIS would be forced to discontinue its program of allowing the operation of privately owned quarantine facilities for ruminants, a development that would hamper U.S. animal import activities.

- 7. Explain any special circumstances that require the collection to be conducted in a manner in consistent with the general information guidelines in 5 CFR 1320.5.
 - requiring respondents to report information to the Agency more often than quarterly;

Daily Log

For purposes of security, facility operators must maintain a daily log to record the entry and exit of all persons entering and leaving the facility while quarantine is in progress.

 requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;

Daily Log

These logs must be made available to an APHIS representative upon request, and must be kept for 2 years following the release of the ruminants from quarantine.

There are no other special circumstances associated with this collection of information.

This information collection is conducted in 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 2008, APHIS engaged in the productive consultations with the following individuals concerning the information collection activities associated with this program:

Ridgeway F. Shinn, III Bakewell Reproductive Center P.O. Box 441 Hardwich, MA 93453 ridge@bakewellrepro.com (413) 477-6500

L.W. Samples, V.M.D P.O. Box 52 Hummelstown, PA 17036-0052 (717) 566-8294 Dr. Thomas J. Holt, State Veterinarian Division of Animal Industry Florida Department of Agriculture and Consumer Services 407 South Calhoun Street, Room 335, Mayo Building Tallahassee, Fl 32399 (850)-410-0900

On Wednesday, November 5, 2008, pages 65821 – 65822, 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 of 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 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 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 0MB Form 83-1.

See APHIS Form 71. Public Burden estimates were developed from discussions with the owner/operator of the privately owned quarantine facilities for ruminants.

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

Respondents are owners/operators of privately owned quarantine facilities for ruminants. APHIS estimates the total annualized cost to these respondents to be \$4,753.00 APHIS arrived at this figure by multiplying the hours of estimated response time (162 hours) by the estimated average hourly wage of the above respondents (\$29.34). APHIS determined the estimated hourly wage from the U.S. Department of Labor, Bureau of Labor Statistics Report - National Compensation Survey: Occupational Wages in the United States, July 2006. See http://www.bls.gov/oes/current/oes291131.htm.

13. Provide estimates 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 and 14). The cost estimate should be split in to two components: (a) a total capital and startup cost component annualized over its excepted useful life; and (b) a total operation and maintenance and purchase of services component.

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

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

The annualized cost to the Federal Government is estimated at \$4348.00. (See APHIS Form 79.)

15. Explain the reasons for any program changes or adjustment reported in Items 12 or 14 of the 0MB Form 83-1.

The respondents decreased to 3 but the annual responses increased to 155 because of the change in responses p/respondent for the daily log which increased to 50 responses per respondent during the year. Also, APHIS is now including the review, research, and development of the responses of the application in the burden time; whereas APHIS previously only tracked the time it took to fill out the report. The Daily Log was counted only as recordkeeping and should have been reporting burden, too.

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.

There are no forms associated with this information collection.

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

APHIS certifies compliance with all provisions of the Act.

B. Collections of Information Employing Statistical Methods

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