Final revision 9-12-2006

**Importation of Etiologic Agents**
**(42 CFR 71.54)**
**OMB Control No. 0920-0199**

**Supporting Statement**

## A. Justification

This is a request for revision to OMB Control No. 0920-0199, Importation of Etiologic Agents. The data collection and reporting requirements are required under 42 CFR Part 71.54. CDC is requesting a 3-year approval for this data collection. A copy of these regulations is found in Attachment 1.

### 1. Circumstances Making the Collection of Information Necessary

The Foreign Quarantine Regulations (42 CFR Part 71) set forth provisions to prevent the introduction, transmission, and spread of communicable disease from foreign countries into the United States. Subpart F – Importations - contains provisions for importation of etiologic agents, hosts, and vectors (42 CFR Part 71.54, Attachment 1), requiring persons that import or distribute after importation these materials to obtain a permit issued by the Centers for Disease Control and Prevention (CDC). To carry out this provision, CDC has developed two forms for application for a permit. One form, the "Application for Permit to Import or Transport Etiologic Agents, Hosts, or Vectors of Human Disease" is used to request permits for the importation and subsequent distribution after importation of etiologic agents, hosts, or vectors of human disease (Attachment 3). This form requests applicant and sender contact information; description of material for importation; facility isolation and containment information; and personnel qualifications. The second form, the "Application for Permit to Import or Transport Live Bats" is used to request importation and subsequent distribution after importation of live bats (Attachment 3). This form requests applicant and sender contact information; a description and intended use of bats to be imported; facility isolation and containment information; and personnel qualifications.

### 2. Purpose and Use of Information Collection

The purpose of this information is to protect the public's health by monitoring the importation of etiologic agents. Any imported etiologic agents coming within the provisions of 42 CFR 71.54 will not be released prior to receipt by the US Customs Service of a permit issued by the Director of CDC, or her authorized representative. In addition, the provision sets minimum packaging and labeling requirements such as infectious materials imported into this country must be packaged to withstand breakage and leakage of contents, and labeled, as specified in the following federal regulations: USPHS 42 CFR Part 72 - Interstate Shipment of Etiologic Agents and DOT 49 CFR PART 173 - Transportation of Etiologic Agents. For international shipments, the International Air Transport Association (IATA) Dangerous Goods Regulations should be consulted.

Information is submitted to CDC as required by the provisions of 42 CFR 71.54 for issuance of permits by CDC to importers or distributors after importation of etiologic agents, hosts, or vectors of human disease. The information is kept in a database which consists of permitted entities importing or receiving etiologic agents. This database is safeguarded; paper records are kept in locked files. Electronic data files are password protected and stored in a restricted access location. Only a small number of staff with the CDC Select Agent Program has access to the information, and disclosure of information is stringently limited.

**3. Use of Improved Information Technology and Burden Reduction**

The electronic forms are available at the CDC website in pdf and pdf-fillable formats. Applications may be mailed or sent by fax. Using a pdf-fillable format, it will be possible for respondents to save the document to the applicant's local drive, complete the form, and then mail or fax the application to CDC. The use of electronic form will facilitate a reduction in burden for those respondent applicants who must submit more than one form to CDC.

**4. Efforts to Identify Duplication and Use of Similar Information**

42 CFR 71.54 specifies that the importation permit is granted by the Director, CDC or her authorized representative. No other component of HHS is involved in these procedures. The only way to obtain the necessary information is from the applicant or the carrier.

**5. Impact on Small Businesses and Other Small Entities**

Collection of information may involve some small businesses or other small entities, but the burden has been limited to providing minimal information on forms, verifying information by telephone, and mailing information to the appropriate parties. CDC has made every effort to ensure that the information collection is the minimal amount necessary to meet the requirements of the law and places a minimal burden on all parties involved.

**6. Consequences of Collecting the Information Less Frequently**

There are legal obstacles to reducing the burden by collecting this information less frequently. The purpose of this information collection is to meet mandated regulatory requirements. If this information were collected less frequently, it would not be possible for CDC to carry out its commitments to protect the public health as mandated by these regulations.

**7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

There are no special circumstances relating to the guidelines of 5 CFR 1320.5.

**8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside**

**the Agency**

**A8A.** A **"60 Day Federal Register Notice"** was published in the Federal Register on May 18, 2006, Vol. 71, No. 96, Pages 28868-28869. A 60 day comment period was given for public comments. No public comments were received. A copy of the Notice is found in Attachment 2.

**A8B. Consultation Outside the Agency**
There has been no consultation outside the agency due to the delegation of responsibilities to the Director of CDC as described herein.

**9. Explanation of Any Payment or Gift to Respondents**

Respondents will not receive any payment or gift.

**10. Assurance of Confidentiality Provided to Respondents**

The CDC/ATSDR Privacy Act Officer has reviewed this application and has determined that the Privacy Act is not applicable to this data collection. While minimum identifiable information is being collected, respondents are answering in their roles as importers or shippers of etiologic agents and will not be providing personal information. The information is kept in a database which consists of permitted entities importing or receiving etiologic agents. This database is safeguarded; paper records are kept in locked files. Electronic data files are password protected and stored in a restricted access location. Only a small number of the Select Agent Program staff (CDC FTEs and contractors) has access to the information, and disclosure of information is stringently limited. As outlined in the contractors' statement of work, the contractors assigned to the Select Agent Program shall not release any information pertaining to the select agent program, specific laboratories, and other sensitive, confidential and proprietary information, without prior approval from the CDC. The CDC has determined that making this information available through a public database could compromise one of the primary purposes of the rule. Therefore, CDC has decided it will not create publicly available databases of the information referenced in 42 CFR Sec. 71.54.

The CDC will follow its established policies and procedures in releasing and/or withholding trade secret and/or confidential or financial information, in accordance with the Freedom of Information Act.

**11. Justification for Sensitive Questions**

This data collection does not include personal questions of a sensitive nature.

**12. Estimates of Annualized Burden Hours and Costs**

Based on past experience, we estimate that there will be approximately 2,300 applications for permit requests per year and that the average response time to complete this questionnaire is 20 minutes. The questionnaire needs to be completed only as needed by the applicant. Amended permits are issued more frequently if pertinent information changes.

Table A12A. Estimate of Annualized Burden Hours

| CFR Section | No. of Respondents | No. of Responses per Respondent | Avg. Burden per Response (in hrs.) | Hourly Burden |
|---|---|---|---|---|
| 71.54 Application Permit for Etiologic Agents | 2,300 | 1 | 20/60 | 766 |
| Total | 2,300 | | | 766 |

Table A12B. Estimate of Annualized Cost to Respondent

| CFR Section | No. of Respondents | Frequency of Response | Hourly Wage Rate | Respondent Cost |
|---|---|---|---|---|
| 71.54 Application Permit | 2,300 | 1 | $57.83 | $44,297.78 |
| Total | 2,300 | | | $44,297.78 |

To estimated costs to respondents, CDC assumed that the hourly burden would be evenly split between managerial staff and clerical staff. CDC assumed an average hourly respondent labor rate (including fringe and overhead) of $86.09 for managerial staff and $29.57 for clerical staff. To calculate the mean hourly rate, we averaged these two figures for an hourly wage rate of $57.83. These rates were obtained from the Bureau of Labor Statistics, from the 2000 Occupational Employment Statistics Survey by Occupation.

**13. Estimates of Other Total Annual Cost Burden to Respondents or RecordKeepers**

Respondents incur no capital or maintenance costs. The only costs incurred to respondents are those associated with telephone calls, mailing, and fax transmissions. All of these costs are part of normal business expenses.

**14. Annualized Cost to the Government**

The total estimated cost for implementing these regulatory activities is $156,678. This estimate includes 2 full-time Federal Employees (FTE) serving as Inspectors at a GS 12 level, with 100% of their time devoted to the collection of the importation forms, and additional costs as shown below.

**FY 2006 Annualized Government Cost**

| | | |
|---|---|---|
| Personnel: | 2 FTEs | $144,428 |
| Travel: | | None |
| Contractual: | | None |
| Equipment: | | $10,000 |
| Supplies: | | $750 |
| Printing: | | $500 |
| Transport (shipping & mailings): | | $1,000 |
| **Total:** | | **$156,678** |

**15. Explanation for Program Changes or Adjustments**

This submission includes no burden changes from the previous submission. The revisions to the data collection are primarily changes to the guidance documents and forms to clarify instructions, correct editorial errors from previously approved documents, and reformat the structure of the forms based on the day-to-day processing of these forms.

**16. Plans for Tabulation and Publication and Project Time Schedule**

There are no plans for tabulation and publication of this data. The data collection is used solely to carry out the provisions of the regulation.

**17. Reason(s) Display of OMB Expiration Date is Inappropriate**

None.

**18. Exceptions to Certification for Paperwork Reduction Act Submissions**

None.

**B. Collections of Information Employing Statistical Methods**

This collection of information does not employ statistical methods. The data collection is mandated by 42 CFR 71.54. The importation of etiologic agents, hosts, and vectors of human disease are regulated by 42 CFR 71.54 and requires that the importation of such materials must be accompanied by a permit issued by CDC (Attachments 3 and 4).

**1. Respondent Universe and Sampling Methods**

Not applicable because this collection of information does not employ statistical methods, as described above. All importers of such materials must submit these forms to CDC.

**2. Procedures for the Collection of Information**

To carry out this provision required under 42 CFR Part 71.54, CDC has developed a form for application for a permit. All forms are available on the CDC website.

**3. Methods to Maximize Response Rates and Deal with Nonresponse**

Any person violating any provision of 42 C.F.R. Part 71 shall be subject to a fine of not more than $1,000 or to imprisonment for not more than 1 year.

**4. Tests of Procedures or Methods to be Undertaken**

CDC has not conducted any tests of procedures. However, CDC has made minor revisions to the previously approved forms.

**5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data**

Individuals from CDC who worked together to develop the common data collection instruments are listed below:

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**List of Attachments**

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|---|---|
| Attachment 1 | Importation of Etiologic Agents, Hosts, and Vectors of Human Disease Possession, Use and Transfer of Select Agents and Toxins (42 CFR Part 71.54) |
| Attachment 2 | 60 Day Federal Register Notice |
| Attachment 3 | Data Collection Instruments approved by OMB, August, 2003<br>- Application for Permit to Import or Transport Etiologic Agents, Hosts, or Vectors of Human Disease<br>- Application for Permit to Import or Transport Live Bats |
| Attachment 4 | Revised Data Collection Instruments<br>- Application for Permit to Import or Transport Etiologic Agents, Hosts, or Vectors of Human Disease<br>- Application for Permit to Import or Transport Live Bats |
| Attachment 5 | Listing of revisions to forms and actual forms with tracked changes<br>- Application for Permit to Import or Transport Etiologic Agents, Hosts, or Vectors of Human Disease<br>- Application for Permit to Import or Transport Live Bats |