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. A copy of these regulations is found in Attachment 1. This request reflects revisions to the forms approved in January, 2008. The original forms approved in January, 2008 are found in Attachment 3a and 3b. The "Application for Permit to Import or Transport Live Bats" is not being revised at this time (attachment 4b). The revised form for the "Application for Permit to Import or Transport Etiologic Agents, Hosts, or Vectors of Human Disease" is found in Attachment 4a, the guidance document to assist applicant's on how to fill out the application is found in Attachment 4c, and all revisions made to the form are found in Attachment 5. The revisions to the data collection are primarily changes to forms to clarify instructions, correct editorial errors from previous submission, and reformat the structure of the forms based on the day-to-day processing of these forms. Based on the respondent data from fiscal year 2010, total burden was changed from 767 (previous submission) to 670 to accurately reflect the total number of applications that the Program should receive. We estimate that there will be approximately 2,010 applications for permit requests per year.

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 3a, old form, attachment 4a, new form). 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 3b and 4b). 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. The revisions to the data collection are primarily changes to forms to clarify instructions, correct editorial errors from previous submission, and reformat the structure of the forms based on the day-to-day processing of these forms. Based on the respondent data from fiscal year 2010, total burden was changed from 767 (previous submission) to 670 to accurately reflect the total number of applications that the

Program should receive. CDC is requesting a 3-year approval for this data collection.

Privacy Impact Assessment

Overview of Data Collection System
Information is submitted through the requested forms 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 Select Agent Program has access to the information, and disclosure of information is stringently limited. The information is maintained for 10 years.

Items of Information to be Collected
Information is being collected from potential permittees that have a legitimate use of materials so be imported under permit as required under 42 CFR 71.54. The following business information is collected from the potential permittee: name, mailing address, phone numbers, and email address.

Identification of Website(s) and Website Content Directed at Children Under 13 years of Age
Information is submitted through the requested forms 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 forms are available to applicant's on a webpage available to the public (http://www.cdc.gov/od/eaipp/importApplicationForms.htm). This webpage is not directed at children under 13 years of age.

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, hosts, or vectors of human disease. 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 his 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.

The revisions to the data collection are primarily changes to forms to clarify instructions, correct editorial errors from previous submission, and reformat the structure of the forms based on the day-to-day processing of these forms.

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 Select Agent Program has access to the information, and disclosure of information is stringently limited.

Privacy Impact Assessment Information

Information is being collected from potential permittees that have a legitimate use of materials so be imported under permit as required under 42 CFR 71.54. The following business information is collected from the potential permittee: name, mailing address, phone numbers, and email address.

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 emailed, mailed or sent by fax. At this time 0% of respondents involve automated data collection. Using the pdf-fillable form, the applicant will be able 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 forms 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 his 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. Since this is a federally mandated regulatory requirement collecting the information less frequently would interfere with CDCs ability to monitor the import or transport of bats, etiologic agents, hosts, or vectors of human disease. Respondents will respond to data collection annually.

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 July15, 2010, Vol. 75, No. 135, Pages 41205-41206. There were no public comments.

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 submission has been reviewed by Information Collection Review Office (ICRO), who determined that the Privacy Act does not apply 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 following information is being collected on behalf of the applicant's employer to receive a permit as required under 42 CFR 71.54. The applicant's business information is obtained: name, mailing address, phone numbers, and email address. 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 outline 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 applicants are instructed on how the information will be used and safeguarded based on the guidance document available at http://www.cdc.gov/od/eaipp/importApplicationForms.htm.

This is a mandatory information collection from potential permittees that have a legitimate use of materials to be imported under permit as required under 42 CFR 71.54. CDC will follow its established policies and procedures in release of information in accordance with the Freedom of Information Act. As outlined in the provisions of The Foreign Quarantine Regulations (42 CFR Part 71), 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.

IRB Approval
IRB approval is not required for this data collection.

Privacy Impact Assessment Information
The following information is being collected on behalf of the applicant's employer to receive a permit as required under 42 CFR 71.54. The applicant's business information is obtained: name, mailing address, phone numbers, and email address.

11. Justification for Sensitive Questions

This data collection does not include sensitive questions. The following information is being collected from potential permittees that have a legitimate use of material that requires a permit under 42 CFR 71.54.

12. Estimates of Annualized Burden Hours and Costs

Based on the respondent data from fiscal year 2010, total burden was changed from 767 (previous submission) to 670 to accurately reflect the total number of applications that the Program should receive. We estimate that there will be approximately 2,010 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

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Applicant	71.54 Application for Permit to Import or Transport Etiologic	2000	1	20/60	667

	Agents, Hosts, or Vectors of Human Disease				
Applicant	71.54 Application for Permit to Import or Transport Live Bats	10	1	20/60	3
Total					670

Table A12B. Estimate of Annualized Cost to Respondent

Type of Respondent	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rates	Total Respondent Costs
Applicants	2000	1	20/60	667	34.33	$22,898.00
Applicants	10	1	20/60	3	34.33	$103.00
Total				670		$23, 001.00

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 $42.67 for managerial staff and $25.99 for clerical staff. To calculate the mean hourly rate, we averaged these two figures for an hourly wage rate of $34.33. These rates were obtained from the Bureau of Labor Statistics, from the 2010 Occupational Employment Statistics Survey by Occupation (http://www.bls.gov/oes/).

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 $227,953. This estimate

includes 3 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 2010 Annualized Government Cost

Personnel:	3 FTEs	$215,703
Travel:		None
Contractual:		None
Equipment:		$10,000
Supplies:		$750
Printing:		$500
Transport (shipping & mailings):		$1,000
Total:		**$227,953**

15. Explanation for Program Changes or Adjustments

Based on the respondent data from fiscal year 2010, total burden was changed from 767 (previous submission) to 670 to accurately reflect the total number of applications that the Program should receive. The revisions to the data collection are primarily changes to forms to clarify instructions, correct editorial errors from previous submission, 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.

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.
http://www.cdc.gov/od/eaipp/importApplicationForms.htm

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.

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

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, January, 2008
	a- Old Form Permit to Import or Transport Etiologic Agents, Hosts, or Vectors of Human Disease
	b- Old Form Permit to Import or Transport Live Bats
Attachment 4	Revised Data Collection Instruments
	a- Revised Form Permit to Import or Transport Etiologic Agents, Hosts, or Vectors of Human Disease
	b- No Changes Permit to Import or Transport Live Bats (No changes)
	c- Guidance Document for the Completion of the Revised Form Permit_to_Import_or_Transport_Etiologic_Agents_Hosts_or_Vectors_of_Human_Disease.doc
Attachment 5	Listing of Revisions to Forms
	- Application for Permit to Import or Transport Etiologic Agents, Hosts, or Vectors of Human Disease