Requirements for a Special Permit to Import Cynomolgus, African Green, or Rhesus Monkeys into the United States
(OMB Control No. 0920-0263)

Request for Extension of Currently Approved Data Collection
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Request for Extension

A. Justification

1. Circumstances Making the Collection of Information Necessary

This is a request for extension of a previous approved data collection. Approval is requested for 3 years.

Section 361 of the Public Health Service Act (42 USC 264) (Attachment 1) authorizes the Secretary of Health and Human Services to make regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States. Existing regulations governing quarantine activities (42 CFR 71.53) (Attachment 2) provide for the registration of importers of nonhuman primates by the Director, Centers for Disease Control and Prevention (CDC), contingent upon the importers meeting certain recordkeeping, reporting, and disease control requirements to be established by the Director. Those recordkeeping, reporting, and disease control requirements are approved under OMB Control No. 0920-0134 (Foreign Quarantine Regulations).

Beginning in 1989, numerous monkeys imported into the U.S. were found to have been infected with a filovirus related to Ebola virus from Africa. This virus has been isolated directly from Cynomolgus monkey blood and tissues, and antibody to the virus has been detected in Cynomolgus, African green, and rhesus monkeys.

On January 19, 1990, CDC published interim guidelines for handling nonhuman primates during transit and quarantine in the "Morbidity and Mortality Weekly Report". Based on additional developments during the next two months, CDC notified all importers in a letter dated March 15, 1990, that compliance with these isolation and quarantine standards was a mandatory condition for continued registration as an importer of nonhuman primates under 42 CFR 71. On March 23, 1990, an announced public meeting was held in Atlanta, Georgia, to allow all interested parties to comment concerning (1) actions taken to date to prevent the importation of filoviruses into the United States and their transmission to animal handlers; (2) the potential impact of the imposition of a temporary ban on the importation into the United States of Cynomolgus monkeys; and (3) additional disease control measures.

On April 4, 1990, CDC reported that four animal handlers at a quarantine facility in the United States had demonstrated serologic evidence of recent infection with the strain of this virus isolated from infected Cynomolgus monkeys. Serologic evidence indicated that approximately 5-10% of Cynomolgus, African green, and rhesus monkeys coming into

the United States had previously been infected with a filovirus – regardless of their origins in Africa or Asia (Philippines, Indonesia, and China).

Considering the available information, the Director of CDC concluded that these three species are capable of being an animal host or vector of human disease. He further concluded that until further information can be obtained about the risk of human illness following infection and about the means of transmission of filoviruses from monkeys to humans, public health practice requires that more stringent precautions be applied to the importation of these three species.

On April 20, 1990, after considering information presented during and following the March 23rd public meeting and other relevant information, the Director of CDC established a special permit procedure (55 FR 15210) (Attachment 3) under the authority of Sections 361-368 of the Public Health Service Act and 42 CFR 71.54. To receive a special permit to import Cynomolgus, African green, and/or Rhesus monkeys, a registered importer of nonhuman primates must submit to the Director of CDC a written plan detailing the steps that will be taken to prevent exposure of persons and animals during the entire importation and quarantine process for the arriving nonhuman primates. This plan must be submitted to the Director of CDC at least 30 days prior to the proposed importation. The plan is evaluated by the Director of CDC and additional information or clarification may be requested if needed. Importation cannot occur until receipt of written approval of the plan by the Director of CDC.

Since May 1990, CDC has monitored the arrival and/or uncrating of certain shipments of nonhuman primates imported under a special permit. Once CDC is assured, through the monitoring process, that the provisions of a special permit plan are being followed and that the importer is demonstrating the use of adequate disease control practices, the special permit is extended to cover the receipt of addition shipments under the same plan for a period of 180 days. This extended period eliminates the burden on importers to repeatedly report identical information, requiring only that specific shipment itineraries and information on changes to the plan which require approval be submitted.

The application process for registration of importers of nonhuman primates (OMB Control No. 0920-0134) was unchanged by the special permit requirements and remains unchanged in this request. The information required for a special permit to import Cynomolgus, African green, and/or Rhesus monkeys is separate from and in addition to the process for application to become a registered importer. This request for review and approval covers only the special permit procedures. CDC is in the process of revising its quarantine regulations. However, any revisions to 42 CFR Part 71 will not affect the requirements for special permit to import these monkeys.

Privacy Impact Assessment

No information in identifiable form is being collected.

2. Purpose and Use of Information Collection

Under the current special permit arrangement, registered importers must submit a plan to CDC for the importation and quarantine of the specific monkeys covered if they wish to import them. The plan must address disease prevention procedures to be carried out in every step of the chain of custody of such monkeys, from embarkation in the country of origin to release from quarantine. Information such as species, origin and intended use for the monkeys, transit information, isolation and quarantine procedures, and procedures for testing of quarantined animals is needed by CDC to make public health decisions. This information enables CDC to evaluate compliance with the standards and determine whether the measures being taken are adequate to prevent exposure of persons and animals during importation. CDC does not have a standard form for this data collection; rather, importers develop and submit a plan which includes the information above.

The information collected in the implementation of the special permit procedure is used to assess the importer's ability to contain potentially infectious material capable of causing serious disease outbreaks in humans. The collection and utilization of this information are essential to ensure implementation of disease control measures to prevent serious outbreaks of human disease.

3. Use of Improved Information Technology and Burden Reduction

The application for special permit can be submitted via email or facsimile, as well as via regular mail or expedited delivery, provided all necessary information is supplied. Use of improved information technology would not further reduce the burden.

4. Efforts to Identify Duplication and Use of Similar Information

No duplication of or similar information exists. Although CDC has information which was previously submitted by each registered importer as part of the application process, CDC does not have the specific information required to make current and critical health decisions. This information can only be collected from individual importers.

5. Impact on Small Businesses or Other Small Entities

The burdens imposed have been reduced to the absolute minimum necessary for CDC to make informed decisions to protect the public and the health of those who may come in contact with imported nonhuman primates. Based on additional knowledge gained as a result of information collected, the burden has been reduced since the original submission. To aid small businesses, CDC is willing to discuss simplification of the submission with individual businesses.

6. Consequences of Collecting the Information Less Frequently

The frequency of data collection is determined by the number of times an importer wishes to import Cynomolgus, African green, and/or Rhesus monkeys. Since monitored

compliance with disease control requirements stipulated in an approved special permit now results in granting an extended 180-day special permit, the frequency of data collection has been significantly reduced. Rather than a complete submission for each shipment, only a specific itinerary and any changes requiring approval must be submitted during the extended permit period. There are no legal obstacles to reducing the burden.

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

As discussed in A.6., frequency of data collection is inconsistent with the guidelines. Proprietary information may be submitted as part of the application for special permit but should be noted as proprietary. CDC does share portions of applications publicly (not proprietary information) in order to expedite discussion regarding developing technical issues on appropriate quarantine and disease prevention methodology.

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

A. A Federal Register Notice announcing the extension of the data collection was published on 12/06/2007, Vol. 72, No. 234, page 68887 (Attachment 4). There was one public comment. A copy of that comment and CDC's response is found in Attachment 5.

B. There have been no other formal consultations since the public meeting on March 23, 1990. CDC does keep interested parties, including other Federal agencies, advised of new situations and requirements.

9. Explanation of Any Payment or Gift to Respondents

Not applicable

10. Assurance of Confidentiality Provided to Respondents

This submission has been reviewed by the CDC Information Collection Review Office (ICRO). The ICRO has determined that the Privacy Act is not applicable. The applicable System of Records Notice is 09-20-0171. Importers do not provide personal information on themselves but rather provide information on the measures taken to prevent exposures of persons and animals during the importation and quarantine process for arriving nonhuman primates and the use of adequate disease control practices. All information received from importers is stored in a secure (locked) data storage room. Only select program staff have keys to this room.

Privacy Impact Assessment Information

No information in identifiable form is being collected.

11. Questions of a Sensitive Nature

There are no questions of a sensitive nature in this data collection.

12. Estimates of Annualized Burden Hours and Costs

A. Respondents are registered importers (commercial or not-for-profit entities) of Cynomolgus, African green, and/or Rhesus monkeys who seek a special permit to import these nonhuman primates.

Respondent	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Businesses (limited permit)	2	5	30/60	5
Businesses (extended permit)	3	5	10/60	2.5
Organizations (extended permit)	15	5	10/60	12.5
Total				20

B. The burden imposed by the permit application is based on the estimated amount of time needed to perform the requirement, multiplied by the number of responses. Twenty respondents are estimated to submit an average of 5 responses each. Respondents operating with established special permits would normally not need to make full submissions (30 minutes per response); new permit holders, estimated to be fewer than 5 in number, would each make no more than 2 full submissions. All remaining submissions would be itinerary and/or change information only (only 10 minutes per response. The estimated total cost to the public is $1,400. These estimates are based on experience with the information requirements associated with existing application and review processes, and increases in the number of importations. The application process is a combined effort between staff veterinarians and facility directors. The hourly wage for these individuals range from $84.12 per hour to as much as $206.19 per hour. We have chosen to use $112.00 per hour as the hourly wage rate as a reasonable estimation for cost to respondent. All registered importers of nonhuman primates are required by 42 CFR Part 71.53 to maintain certain disease control procedures and keep certain records. Standard business practices indicated that importers already keep records on the origin, transportation, and disposition of animals. Thus, CDC asks for information which should already be maintained by the importers and need only be assembled and reported. The estimate of burden hours and costs reflects assembling and reporting only.

Respondent	No. of Respondents	Responses per Respondent	Average Burden per Response (in hours)	Hourly Wage Rate	Total Respondent Costs
Businesses (limited permit)	2	5	30/60	$112.00	$560.00

Respondent	No. of Respondents	Responses per Respondent	Average Burden per Response (in hours)	Hourly Wage Rate	Total Respondent Costs
Businesses (extended permit)	3	5	10/60	$112.00	$280.00
Organizations (extended permit)	15	5	10/60	$112.00	$1,400.00
Total					$2,240.00

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no capital and maintenance costs.

14. Annualized Cost to the Government

The estimated cost to the Federal government is $5,000.00. This estimate is based on experience with the information requirements associated with existing application and review processes and reflects CDC staff time for the review and decision-making process only. This amount includes two site visits and an estimated time of 24 hours of paperwork and facility review to complete the registration process.

15. Explanation for Program Changes or Adjustments

This request is for an extension without change. The burden has not changed from the burden shown in the current inventory.

16. Plans for Tabulation and Publication and Project Time Schedule

These are recurring data collections, the time schedules for which are determined by importers' arrangements to import nonhuman primates. Data are not collected for statistical use. There are no current plans to publish any information received in the special permit application process.

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

Not applicable

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

B. Collection of Information Employing Statistical Methods

Statistical methods do not apply to this data collection.

A registered importer must request a special permit Cynomolgus, African green, or Rhesus monkeys into the U.S. To receive the special permit, the importer must submit a written plan to the Director of CDC which specifies steps that will be taken to prevent exposure of persons and animals during the entire importation and quarantine process for the arriving nonhuman primates. This includes disease prevention procedures in every step of the chain of custody of these monkeys from embarkation in the country of origin to release from quarantine. Information such as species, origin, and intended use for monkeys, transit information, isolation and quarantine procedures, and procedures for testing of quarantined animals. CDC evaluates compliance with the standards and determines whether the measures being taken are adequate to prevent exposure of persons and animals during importation.

CDC monitors at least 2 shipments of nonhuman primates to be assured that the provisions of a special permit are being followed by a new permit holder. Once CDC is assured that adequate disease control practices are being used by new permit holders, the special permit can be extended to cover the receipt of additional shipments under the same plan for a period of 180 days and may be renewed upon request.

Registered importers are commercial or not-for-profit importers of nonhuman primates.

List of Attachments

Attachment 1: 42 USC 264: Regulations to Control Communicable Diseases

Attachment 2: 42 CFR 71.53: Nonhuman Primates

Attachment 3: 55 FR 15210: Special Permit Procedure

Attachment 4: 60 day Federal Register Notice

Attachment 5: Public comments to 60d FRN and CDC response

Attachment 6: Data elements required for this information collection request