

**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
April 2011**

Contact:

Paulette Ford-Knights

Office of Policy and Planning

National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)

Centers for Disease Control and Prevention

1600 Clifton Road, N.E., MS D-76

Atlanta, Georgia 30333

Phone: (404) 639-4895

Fax: (404) 639-4146

Email: pbf7@cdc.gov

Table of Contents

A. Justification

1. Circumstances Making the Collection of Information Necessary
2. Purpose and Use of Information Collection
3. Use of Improved Information Technology and Burden Reduction
4. Efforts to Identify Duplication and Use of Similar Information
5. Impact on Small Businesses or Other Small Entities
6. Consequences of Collecting the Information Less Frequently
7. 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
9. Explanation of Any Payment or Gift to Respondents
10. Assurance of Confidentiality Provided to Respondents
11. Justification for Sensitive Questions
12. Estimates of Annualized Burden Hours and Costs
13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers
14. Annualized Cost to the Federal Government
15. Explanation for Program Changes or Adjustments
16. Plans for Tabulation and Publication and Project Time Schedule
17. Reason(s) Display of OMB Expiration Date is Inappropriate
18. Exceptions to Certification for Paperwork Reduction Act Submissions

B. Collection of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods
2. Procedures for the Collection of Information
3. Methods to Maximize Response Rates and Deal with No response
4. Tests of Procedures or Methods to be Undertaken
5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

C.

**Requirement of 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

The Centers for Disease Control and Prevention (CDC) is requesting a 3-year request for extension of a previously approved data collection.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Background

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 non-human 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 non-human 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 non-human 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 non-human 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 non-human 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 non-human 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 additional 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 non-human 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 Overview of the Data Collection System

This data is collected from importers of non-human primates who choose to import *Cynomolgus*, African Green, and/or Rhesus monkeys under the authority given to CDC

in 42 CFR Part 71.53. The data will be used by CDC to prevent the introduction or spread of communicable disease into the United States via Non-Human Primate. The information collected from importers will not be shared.

No information in identifiable form is being collected in this information collection request. Importers do not provide personal information, but rather provide information on the measures taken to prevent exposures of persons and animals during the importation and quarantine process for arriving non-human primates and the use of adequate disease control practices.

This information collection request is classified as an extension, and so no changes in the type or amount of information, or the process by which that information is collected, is changing. Previous submissions for the Special Permit to Import Cynomolgus, African Green, or Rhesus Monkeys into the United States have 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.

All information received from importers is stored in a secure (locked) data storage room. Only select program staff are engaged in the importer related activities have keys to this room. No contractors are used in the collection of information, as all paperwork already exists with the importers and is simply compiled and reported to CDC.

Items of Information to be Collected

Data collected from importers of non-human primates who choose to import Cynomolgus, African Green, and/or Rhesus monkeys under the authority given to CDC in 42 CFR Part 71.54 will be used by CDC to prevent the introduction, transmission, or spread of communicable disease from foreign countries into the United States via non-human primate.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

Under no circumstances will CDC sponsored data collection, websites or internet content directed at children under the age of 13.

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.

Privacy Impact Assessment

This data is collected from importers of non-human primates who choose to import Cynomolgus, African Green, and/or Rhesus monkeys under the authority given to CDC in 42 CFR Part 71.54. The data will be used by CDC to prevent the introduction, transmission, or spread of communicable disease from foreign countries into the United States via non-human primate. The information collected from importers will not be shared.

No information in identifiable form is being collected in this information collection request. Importers do not provide personal information, but rather provide information on the measures taken to prevent exposures of persons and animals during the importation and quarantine process for arriving non-human primates and the use of adequate disease control practices.

This information collection request is classified as an extension, and so no changes in the type or amount of information, or the process by which that information is collected, is changing. Previous submissions for the Special Permit to Import Cynomolgus, African Green, or Rhesus Monkeys into the United States have 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.

All information received from importers is stored in a secure (locked) data storage room. Only select program who are engaged in the importer related activities have keys to this room. No contractors are used in the collection of information, as all paperwork already exists with the importers and is simply compiled and reported to CDC.

3. Use of Improved Information Technology and Burden Reduction

The application for special permit can be submitted via email, as well as via facsimile, 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. CDC is currently the only regulatory agency authorized to collect this information for the purposes of protecting public health, which it accomplishes by preventing the importation of disease in Non Human Primates. 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 non-human 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.7., 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. CDC's procedures to protect confidential information fully comply with the regulation 5 CFR 1320.5.

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 12/07/2010, Vol. 75, No. 234, pages 76007(Attachment 4). There was one public comment. A copy of that comment and CDC's response is found in Attachment 4.

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

No monetary incentives or gifts are provided to respondent. Respondents must comply with the special permit requirements to import Cynomolgus, African Green, or Rhesus Monkeys into the United States or they are not permitted to import these animals.

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 has keys to this room.

IRB Approval

IRB approval is not required for this study.

Privacy Impact Assessment Information

A. No information in identifiable form is being collected for this information collection request. Importers do not provide personal information, but rather provide information on the measures taken to prevent exposures of persons and animals during the importation and quarantine process for arriving non-human primates and the use of adequate disease control practices. This information collection request is classified as an Extension, and so no changes in the type or amount of information, or the process by which that information is collected, is changing. Previous submissions for the Special Permit to Import Cynomolgus, African Green, or Rhesus Monkeys into the United States have 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.

B. All information received from importers is stored in a secure (locked) data storage room. Only select program staff are engaged in the importer related activities have keys to this room. No contractors are used in the collection of information, as all paperwork already exists with the importers and is simply compiled and reported to CDC.

C. Any importer who intends to import Cynomolgus, African Green, or Rhesus Monkeys into the United States must comply with the requirements of the special permit. By requesting the special permit, a potential importer is providing consent to this information collection and is aware of the reason for submitting the required documentation. CDC has no plans for sharing the information submitted for the special permit.

D. The information requested from the importers is voluntary. The information is required only if the importer makes the voluntary determination that it wants to import Cynomolgus, African Green, or Rhesus Monkeys into the United States.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature in this data collection. Importers do not provide personal information, but rather provide information on the measures taken to prevent exposures of persons and animals during the importation and quarantine process for arriving non-human primates and the use of adequate disease control practices.

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 non-human primates. 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. We estimate that 20 respondents will 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).

Estimated Annualized Burden Hours

Type of 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	3
Organizations (extended permit)	15	5	10/60	13
Total				21

B. The estimated total cost to the public is \$2,240. 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 non-human 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.

Estimated Annualized Burden Costs

Type of Respondent	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Businesses (limited permit)	2	5	30/60	5	\$112.00	\$560.00
Businesses (extended permit)	3	5	10/60	3	\$112.00	\$280.00
Organizations (extended permit)	15	5	10/60	13	\$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 Federal Government

The Requirements for a Special Permit to Import Cynomolgus, African Green, or Rhesus Monkeys into the United States is administered by the CDC on an ongoing basis, as defined by CDC’s regulatory authorities and responsibilities. The estimated average yearly 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 to the entity filing or renewing a permit and an estimated time of 24 hours of paperwork and facility review to complete the registration process per site visit.

15. Explanation for Program Changes or Adjustments

There are no changes or adjustments for the program. This request is for extension of existing information collections. 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 non-human 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

This section is not applicable to this information collection. There are no forms that outline the data requirements to which the respondent must respond, and so there is no place for the display of the expiration date. All registered importers of non-human 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.

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. No statistical methods are used in 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 non-human 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 non-human 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.

1. Respondent Universe and Sampling Methods

There are no sampling methods employed for this data collection as the importation of these animals is covered by a regulatory requirement. The respondent universe is all animal importers who want to import Cynomolgus, African Green, or Rhesus Monkeys into the United States.

2. Procedures for the Collection of Information

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 non-human 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 non-human 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 non-human primates.

3. Methods to Maximize Response Rates and Deal with No response

The information collected for the Special Permit is required in the event that any registered importer wants to import Cynomolgus, African green, or Rhesus monkeys into the U.S. If the importer does not comply with each part of the Special Permit, a No Response, importation is not permitted. It is in the importers interest to respond to the requirements for the Special Permit if indeed it intends to import the specified animals.

4. Tests of Procedures or Methods to be Undertaken

The information being collected from the importers is defined by regulations and requirements set by CDC. No tests of procedures or questions were preformed.

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

There are no statistical aspects of the information being collected and no statistical consultants were contacted. Collection and review of the information is the responsibility of the Division of Global Migration and Quarantine.

List of Attachments

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

Attachment 2: 42 CFR 71.53: Non-human Primates

Attachment 3: 55 FR 15210: Special Permit Procedure

Attachment 4: 60 day Federal Register Notice and Public comment

Attachment 5: Data elements required for Special Permit to Import Cynomolgus, African Green, or Rhesus Monkeys into the United States.