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

Request for Revision of Currently Approved Data Collection
February 19, 2013

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Request for Revision of Approved Data Collection (expiring 6/30/2014)

The Centers for Disease Control and Prevention (CDC) requests a revision for a currently approved data collection: Requirement of a Special Permit to Import Cynomolgus, African Green, or Rhesus Monkeys into the United States (OMB 0920-0263, expiring 6/30/2014).

As a result of two recent rulemakings, the Requirements for Importers of Nonhuman Primates final rule and the Establishment of User Fees for Filovirus Testing of Nonhuman Primate Liver Samples, CDC is requesting the following changes and adjustments:

1. CDC requests that OMB number 0920-0263 be re-named "Requirements for the Importation of Nonhuman Primates into the United States" to more accurately reflect the type of information that is requested from respondents.
2. To streamline administration of this information collection request, CDC requests that CDC form 75.10A Application for Registration as an Importer of Nonhuman Primates and the documentation requirements, currently approved under OMB number 0920-0134 Foreign Quarantine Regulations, be moved and included in this revision to OMB number 0920-0263. This action places all nonhuman primate information collection requirements into one package administered by CDC.
    a. The transition of CDC form 75.10A to OMB Number 0920-0263, and a downward adjustment to account for the reduction of anticipated importer registrations per year, results in three burden hours transitioning to this collection request.
    b. The addition of the documentation requirements outlined in the revised 42 Code of Federal Regulations part 71.53 and downward adjustments to the number of respondents results in 17 burden hours transitioning to this collection request. Although there is only one new importer anticipated per year, CDC has included an estimated burden for this category because the burden is likely higher the first time the required documentation is compiled, 10 hours versus 30 minutes.
3. CDC is renaming the different portions of the information collected in this information collection to more accurately list the types of forms and documentation CDC collects from importers of nonhuman primates. Therefore, the former information categories of Businesses (limited permit), Businesses

(extended permit), and Organizations (extended permit) are being renamed and reorganized. The information contained in this categories will now be accounted for in the Documentation sections of table 12 A below. This categorization will more accurately reflect CDC's interaction with the importers.

4. CDC also requests a change of an additional 76 hours to account for importer time spent notifying CDC of incoming nonhuman primate shipments and requests by importers for the release of nonhuman primates from quarantine.
5. CDC further requests the addition of the Filovirus Diagnostic Specimen Submission Form for Non-human Primate Materials, which will be used to collect all of the necessary information from nonhuman primate importers to test nonhuman primate liver samples for filovirus and communicate the results of this test. This change adds approximately 50 hours of burden to this information collection request.

The total change in burden requested for this information collection request is 125. The total number of burden hours requested in this revision is 146.

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 currently 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 the 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 71.53. 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 the special permit program. 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.

In February 2013, CDC promulgated two regulations pertaining to the importation of nonhuman primates. The first rule, Establishment of User Fees for Filovirus Testing of Nonhuman Primate Liver Samples (Attachment 4), outlines a process by which importers can send liver tissues to CDC from primates that die during importation from reasons

other than trauma (2/12/2013, Vol.78, No. 29, p.9828). CDC performs these tests due to the absence of a private sector option. The second rule, Requirements for Importers of Nonhuman Primates (Attachment 5) consolidates into 42 CFR 71.53, the requirements previously found in 42 CFR part 71.53 with those found in the Special Permit to Import Cynomolgus, African Green, or Rhesus Monkeys into the United States (2/15/2013, Vol. 78, No. 32 /p. 11522). It also extended the time period for registration/permit renewal from 180 days to 2 years, reducing much of the respondent burden. The Special Permit federal register notice published in 1990 has been withdrawn. The requirements formerly found therein are now incorporated into the revised final rule for 42 CFR 71.53. CDC feels these regulatory changes balance the public health risks posed by the importation of nonhuman primates with the burden imposed on regulating their importation.

Privacy Impact Assessment

Overview of the Data Collection System

This data is collected from importers of non-human primates who choose to import nonhuman primates 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 nonhuman primate. The information collected from importers will not be shared unless in a manner specified below.

On December 13, 2007, CDC published a notice of a new system of records under the Privacy Act of 1974 for its conduct of activities under 42 CFR 71 (72 FR 70867). The data will become part of CDC Privacy Act System of Records 09-20-0171, "Quarantine and Traveler-Related Activities, Including Records for Contact Tracing, Investigation, and Notification under 42 CFR Parts 70 and 71," and may be disclosed to appropriate State or local public health departments and cooperating medical authorities to deal with conditions of public health significance; to private contractors assisting CDC in analyzing and reviewing records; to investigators under certain limited circumstances to conduct further investigations; to organizations to carry out audits and reviews on behalf of HHS; to the Department of Justice for litigation purposes; and to a congressional office assisting individuals in obtaining their records. An accounting of the disclosures that have been made by CDC will be made available to the subject individual upon request. Except for these and other permissible disclosures expressly authorized by the Privacy Act, no other disclosure may be made without the subject individual's written consent.

Sensitive information regarding the identity of nonhuman primate importers and their respective institutions is being collected and could affect a respondent's privacy if there were a breach of information security. However, stringent safeguards are in place to ensure a respondent's privacy including authorized users, physical safeguards, and procedural safeguards. Authorized users: A database security package is implemented on CDC's computer systems to control unauthorized access to the system. Attempts to gain access by unauthorized individuals are automatically recorded and reviewed on a regular basis. Access is granted to only a limited number of physicians, scientists, statisticians, and designated support staff of CDC or its contractors as authorized by the system manager to accomplish the stated purposes for which the data in this system have been collected. Physical safeguards: Access to the CDC facility where the mainframe

computer is located is controlled by a cardkey system. Access to the computer room is controlled by a cardkey and security code (numeric code) system. Access to the data entry area is also controlled by a cardkey system. Guard service in buildings provides personnel screening of visitors. The computer room is protected by an automatic sprinkler system, numerous automatic sensors are installed, and a proper mix of portable fire extinguishers is located throughout the computer room. Computer files are backed up on a routine basis. Hard copy records are stored in locked cabinets at CDC headquarters and CDC Quarantine Stations which are located in a secure area of the airport. Procedural safeguards: Protections for computerized records include programmed verification of valid user identification code and password prior to logging on to the system, mandatory password changes, limited log-ins, virus protection, and user rights/file attribute restrictions. Password protection imposes user name and password log-in requirements to prevent unauthorized access. Each user name is assigned limited access rights to files and directories at varying levels to control file sharing. There are routine daily back-up procedures, and secure off-site storage is available. To avoid inadvertent data disclosure, measures are taken to ensure that all data are removed from electronic medical containing Privacy Act information. Finally, CDC and contract employees who maintain records are instructed to check with the system manager prior to making disclosures of data. When individually identified data are being used in a room, admittance at either CDC or contract sites is restricted to specifically authorized personnel. Privacy Act provisions are included in contracts and the CDC Project Director, contract officers and project officers oversees compliance with these requirements.

Items of Information to be Collected

Data collected from importers of non-human primates who choose to import nonhuman primates under the authority given to CDC in 42 CFR Part 71.53 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.

Registrations of nonhuman importers with CDC will be accomplished using the PDF form 75.10A Application for Registration as an Importer of Nonhuman Primates (Attachment 6). The information collected is limited to identification requirements for the facility requesting registration and the determination of whether the facility possesses the health security capacity required to prevent zoonotic transmission of disease from nonhuman primates to humans. The documentation requirements include all those specified in the revised 42 CFR 42 part 71.53.

Collection of information pertaining to the testing of filovirus in nonhuman primate liver samples will be accomplished using the Filovirus Diagnostic Specimen Submission Form for Non-human Primate Materials (Attachment 7). The information collected in this form is limited to those pieces of information necessary to identify the party requesting the test, payment information, and information related to the sample itself.

2. Purpose and Use of Information Collection

Under the revised 42 CFR 71.53 promulgated, registered importers must submit a plan to CDC for the importation and quarantine of the specific nonhuman primates to be imported. The plan must address disease prevention procedures throughout the chain of custody of such nonhuman primates, from embarkation in the country of origin to release from quarantine. Information such as species, origin and intended use for the nonhuman primates, 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 and determine if adequate measures being taken for the prevention of exposure to 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 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

1. The information collected as outlined in this request will become part of CDC Privacy Act System of Records 09-20-0171, "Quarantine and Traveler-Related Activities, Including Records for Contact Tracing, Investigation, and Notification under 42 CFR Parts 70 and 71," and may be disclosed to appropriate State or local public health departments and cooperating medical authorities to deal with conditions of public health significance; to private contractors assisting CDC in analyzing and reviewing records; to investigators under certain limited circumstances to conduct further investigations; to organizations to carry out audits and reviews on behalf of HHS; to the Department of Justice for litigation purposes; and to a congressional office assisting individuals in obtaining their records. An accounting of the disclosures that have been made by CDC will be made available to the subject individual upon request. Except for these and other permissible disclosures expressly authorized by the Privacy Act, no other disclosure may be made without the subject individual's written consent.

2. Highly sensitive information regarding the identity of nonhuman primate importers and their respective institutions is being collected and could affect a respondent's privacy if there were a breach of information security. However, stringent safeguards are in place to ensure a respondent's privacy including authorized users, physical safeguards, and procedural safeguards.

3. Use of Improved Information Technology and Burden Reduction

The application for registration can be submitted via email, regular mail, or expedited delivery, provided all necessary information is supplied. The form for filovirus testing is submitted using a CDC website. Use of improved information technology would not further reduce the burden. Notification of imports and the request to release from quarantine may be sent by phone, text, email.

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 nonhuman 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 nonhuman primates. Monitored compliance with disease control requirements stipulated in regulation now results in an extended 2-year permit, and thus, 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

The frequency of data collection is inconsistent with the guidelines. Proprietary information may be submitted as part of the application for the 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 CRF 1320.5.

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

A. Two final rules have been published outlining the information requirements contained in this information collection request

1. Establishment of User Fees for Filovirus Testing of Nonhuman Primate Liver Samples: 2/12/2013, Vol.78, No. 29, p.9828
2. Requirements for Importers of Nonhuman Primates (2/15/2013, Vol. 78, No. 32 p. 11522)

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 permit requirements to import nonhuman primates 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 NCEZID has determined that the Privacy Act is applicable. The applicable System of Records Notice is 09-20-0171 Quarantine- and Traveler-Related Activities, Including Records for Contact Tracing Investigation and Notification under 42 CFR Parts 70 and 71. Importers provide limited personal information on themselves. Rather importers provide information on the location of their facilities and 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.

<u>IRB Approval</u>

IRB approval is not required for this information collection.

<u>Privacy Impact Assessment Information</u>

1. This information collection is voluntary. Importers are informed that providing the information is mandatory, as defined in regulation in 42 CFR part 71.53, only if they want to import nonhuman primates into the United States.

2. Any importer who intends to import nonhuman primates into the United States must comply with the requirements of the permit. By requesting the permit, a potential importer gives 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 permit.

3. 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.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature in this data collection. Importers provide limited 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 nonhuman primates who seek approval from CDC for importation. The burden imposed by the registration, permit application, notification, and documentation requirements is based on the estimated amount of time needed to perform the requirement, multiplied by the number of responses. The revised Requirements for Importers of Nonhuman Primates final rule requires importers to re-register every two years instead of every 180 days. This means that only half of the 24 currently registered importers will need to respond to Registration and Documentation requirements in any one year. CDC estimates that one new importer will register with CDC per year. It is likely new importers will require additional time to develop the Documentation necessary to register with CDC, so additional burden hours are requested for New Importers.

CDC estimates the following number of respondents and the respective frequency with which they will need to send information to CDC. The below table reflects operational and programmatic updates and adjustments to increase clarity for respondents regarding specific information collections.

- CDC estimates one new applicant for CDC registration/year will need to make NEW CDC registration (10 minutes).
- 24 CDC-registered importers will need to re-apply every two years for CDC registration (10 minutes each), or 12 importers per year. This estimate is derived

from the current number of CDC-registered importers plus one to account for any new importers.

- CDC estimates one new applicant per year that will need to submit documentation to comply with the revised regulation. CDC estimates the burden of this requirement to be 10 hours.
- 24 CDC-registered importers will need to comply with the documentation requirements as requested by CDC. CDC estimates the burden to update existing documentation to be 30 minutes.
- 25 CDC-registered importers will need to notify CDC before each NHP shipment. This occurs approximately 150 times per year and requires 15 minutes per notification. The number of importers is derived from the current number of CDC-registered importers plus one to account for any new importers.
- 25 CDC-registered importers will need to request release of each NHP from CDC quarantine. This occurs approximately 150 times per year and requires 15 minutes per notification. The number of importers is derived from the current number of CDC-registered importers plus one to account for any new importers.
- CDC estimates that 10 CDC-registered importers will need to submit filovirus samples for testing. CDC estimates this requested filovirus testing will occur on average a total of 150 times per year, with each request for testing taking a respondent 20 minutes each time.

Estimated Annualized Burden Hours

Type of Respondent	Form Name/CFR Reference	# of Respondents	# of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Nonhuman Primate Importer	CDC 75.10A Application for Registration as an Importer of Nonhuman Primates (New Importer)	1	1	10/60	1
Nonhuman Primate Importer	CDC 75.10A Application for Registration as an Importer of Nonhuman Primates (Re-Registration)	12	1	10/60	2
Nonhuman Primate Importer	71.53(g)(1)(iii) and (h) Documentation and Standard Operating Procedures (no	1	1	10	10

	form) (New Importer)				
Nonhuman Primate Importer	71.53(g)(1)(iii) and (h) Documentation and Standard Operating Procedures (no form) (Registered Importer)	12	1	30/60	7
Nonhuman Primate Importer	Recordkeeping and reporting requirements for importing NHPs: Notification of shipment arrival 71.53(n) (no form)	25	6	15/60	38
Nonhuman Primate Importer	Quarantine release 71.53(l) (No form)	25	6	15/60	38
Nonhuman Primate Importer	71.53 (v) Form: Filovirus Diagnostic Specimen Submission Form for Non-human Primate Materials	10	15	20/60	50
Total					146

B. The estimated total cost to the public is $5,986. These estimates are based on experience with the information requirements associated with existing application and review processes, increases in the number of importations, and knowledge of the professions involved in the importing process. The application process is a combined effort between staff veterinarians (http://www.bls.gov/oes/current/oes291131.htm), facility directors (veterinarians at a higher pay rate), and veterinary assistants/laboratory animal caretakers (http://www.bls.gov/ooh/healthcare/veterinary-assistants-and-laboratory-animal-caretakers.htm). CDC has therefore chosen to estimate the cost to the respondents in the following manner:

- The median hourly wage for veterinarians and the median pay for vet caretakers as is used as the cost basis.
- The effort was apportioned by using 75% percentile pay for vets (to account for the high pay rate) and adding in 25% of the response burden as being performed by animal caretakers.
- The result of this estimate is $41.02 per hour, which we have rounded to $41 per hour in the table below.

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	Form Name/CFR Reference	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Nonhuman Primate Importer	CDC 75.10A Application for Registration as an Importer of Nonhuman Primates (New Importer)	1	$41	$41.00
Nonhuman Primate Importer	CDC 75.10A Application for Registration as an Importer of Nonhuman Primates (Re-Registration)	2	$41	$82.00
Nonhuman Primate Importer	71.53(g)(1)(iii) and (h) Documentation and Standard Operating Procedures (no form) (New Importer)	10	$41	$410.00
Nonhuman Primate Importer	71.53(g)(1)(iii) and (h) Documentation and Standard Operating	7	$41	$287.00

Type of Respondent	Form Name/CFR Reference	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
	Procedures (no form) (Registered Importer)			
Nonhuman Primate Importer	Recordkeeping and reporting requirements for importing NHPs: Notification of shipment arrival 71.53(n) (no form)	38	$41	$1,558.00
Nonhuman Primate Importer	Quarantine release 71.53(l) (no form)	38	$41	$1,558.00
Nonhuman Primate Importer	71.53 (v) Form: Filovirus Diagnostic Specimen Submission Form for Non-human Primate Materials	50	$41	$2,050.00
Total		179	$41	$5699.00

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 permit to import nonhuman primates 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 $123,150. This estimate reflects CDC staff time for the review of documentation and notification, and includes costs for 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.

GS-13 @ 50% time	$42,750
GS-13@ 80% time	$68,400
Travel Costs	$12,000
Total	$123,150

15. Explanation for Program Changes or Adjustments

As a result of two recent rulemakings, the Requirements for Importers of Nonhuman Primates final rule and the Establishment of User Fees for Filovirus Testing of Nonhuman Primate Liver Samples, CDC is requesting the following changes and adjustments:

1. CDC requests that OMB number 0920-0263 be re-named "Requirements for the Importation of Nonhuman Primates into the United States" to more accurately reflect the type of information that is requested from respondents.
2. To streamline administration of this information collection request, CDC requests that CDC form 75.10A Application for Registration as an Importer of Nonhuman Primates and the documentation requirements, currently approved under OMB number 0920-0134 Foreign Quarantine Regulations, be moved and included in this revision to OMB number 0920-0263. This action places all nonhuman primate information collection requirements into one package administered by CDC.
    a. The transition of CDC form 75.10A to OMB Number 0920-0263, and a downward adjustment to account for the reduction of anticipated importer registrations per year, results in three burden hours transitioning to this collection request.
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3. CDC also requests a change of an additional 76 hours to account for importer time spent notifying CDC of incoming nonhuman primate shipments and requests by importers for the release of nonhuman primates from quarantine. ?where on burden table?
4. CDC is renaming the different portions of the information collected in this information collection to more accurately list the types of forms and documentation CDC collects from importers of nonhuman primates. Therefore, the former information categories of Businesses (limited permit), Businesses (extended permit), and Organizations (extended permit) are being renamed and reorganized. The information contained in these categories will now be accounted for in the Documentation sections of table 12 A above. This categorization will more accurately reflect CDC's interaction with the importers.

5. CDC further requests the addition of the Filovirus Diagnostic Specimen Submission Form for Non-human Primate Materials (Form 71.53v), which will be used to collect all of the necessary information from nonhuman primate importers to test nonhuman primate liver samples for filovirus and communicate the results of this test. This change adds approximately 50 hours of burden to this information collection request.

The increased burden requested for this information collection request is 125. The total number of burden hours requested in this revision is 146.

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 permit application process.

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

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

List of Attachments

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

Attachment 2: 42 CFR 71.53 Foreign Quarantine

Attachment 3: 55 FR 15210: Special Permit Procedure

Attachment 4: Establishment of User Fees for Filovirus Testing of Nonhuman Primate Liver Samples Final Rule

Attachment 5: Requirements for Importers of Nonhuman Primates Final Rule

Attachment 6: CDC 75.10A Application for Registration as an Importer of Nonhuman Primates

Attachment 7: Filovirus Diagnostic Specimen Submission Form for Non-human Primate Materials