Requirements for the Importation of Nonhuman Primates into the United States

OMB Control No. 0920-0263
Exp 9/30/2017

Supporting Statement A

Request for Revision of Currently Approved Data Collection
April 26, 2017

Contact:

Lee Samuel
Office of Policy and Planning
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., MS C12
Atlanta, Georgia 30333
Phone: (404) 718-1616
Email: llj3@cdc.gov

Table of Contents

Contents

A. Justification....3
1. Circumstances Making the Collection of Information Necessary....3
2. Purpose and Use of Information Collection....5
3. Use of Improved Information Technology and Burden Reduction....5
4. Efforts to Identify Duplication and Use of Similar Information....6
5. Impact on Small Businesses or Other Small Entities....6
6. Consequences of Collecting the Information Less Frequently....6
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5....7
8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency 7
9. Explanation of Any Payment or Gift to Respondents....7
10. Assurance of Confidentiality Provided to Respondents....7
11. Justification for Sensitive Questions....8
12. Estimates of Annualized Burden Hours and Costs....9
13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers. . .13
14. Annualized Cost to the Federal Government....13
15. Explanation for Program Changes or Adjustments....14
16. Plans for Tabulation and Publication and Project Time Schedule....14
17. Reason(s) Display of OMB Expiration Date is Inappropriate....14
18. Exceptions to Certification for Paperwork Reduction Act Submissions....14

Requirements for the Importation of Nonhuman Primates into the United States
(OMB Control No. 0920-0263, Exp 9/30/2017)

Request for Revision/ of Approved Data Collection

- Goal of the study: to continue regulatory oversight of nonhuman primate importers through registration, reregistration, evaluation of standard operating procedures, receiving pre-shipment notification, reviewing requests for releasing shipments from CDC quarantine, and overseeing filovirus testing of nonhuman primates (NHP) when required.
- Intended use of the resulting data: to ensure that NHP importers are meeting CDC regulatory requirements.
- Methods to be used to collect: registration/reregistration form, pre-shipment notification, request for release of shipment from CDC quarantine, evaluation of standard operating procedures.
- The subpopulation to be studied: United States-based importers of nonhuman primates.
- How data will be analyzed: simple tabulations of registered importers, imported NHPs, and filovirus test results.

The Centers for Disease Control and Prevention (CDC) is requesting approval for a set of adjustments to the previously approved burden total for this information collection. These requested adjustments include a reduction in burden in three of the information collections under this approval. The total number of hours requested for this information collection total 922 hours. The adjustments are as follows:

Adjustments:
Based on the number of registered importers and the number of filovirus samples processed by CDC, CDC is adjusting downward the number of burden hours for the following collections:

- Recordkeeping and reporting requirements for importing NHPs: Notification of shipment arrival 71.53(n) (no form): Reduction of two hours
- Quarantine release 71.53(l) (No form): Reduction of two hours
- 71.53 (v): Form: Filovirus Diagnostic Specimen Submission Form for Non-human Primate Materials: Reduction of 17 hours
- 71.53(g)(1)(iii) and (h) Documentation and Standard Operating Procedures (no form) (Registered Importer): Reduction of one hour

A. Justification

1. Circumstances Making the Collection of Information Necessary

Background

The purpose of this submission is to request a revision of a currently approved data collection "**Requirements for the Importation of Nonhuman Primates into the United States"** that expires 09/30/2017.

Section 361 of the Public Health Service Act (PHSA) (42 U.S.C. 264) (Attachment 1) authorizes the Secretary of Health and Human Services to make and enforce regulations necessary to prevent the introduction, transmission or spread of communicable diseases from foreign countries into the United States. Existing regulations governing quarantine activities authorize quarantine officers and other personnel to inspect and undertake necessary control measures with respect to conveyances, persons, and shipments of animals, including nonhuman primates (42 CFR 71.53) (Attachment 3) and etiologic agents in order to protect the public's health. These practices and procedures ensure protection against the introduction and spread of communicable diseases into the United States with a minimum of recordkeeping and reporting requirements, as well as a minimum of interference with trade and travel.

As part of this legal authority, CDC is authorized to access and use entry, entry summary, and manifest data to further its public health mission. CDC is also permitted access to the Automated Commercial Environment (ACE) data pursuant to 6 CFR § 29.8(b) and 49 CFR §1520.11(b), which permit federal employees with a need to know to have access to this data. As a government agency that requires documentation for clearing an import, CDC is submitting this revision to obtain authority to collect electronic information from importers on specific types of animals and cargo over which CDC has authority, notably those found in 42 CFR Part 71. The regulations found at 42 CFR 71.53 authorize this information collection and include reporting and recordkeeping requirements pertaining to the importation of animals, specifically nonhuman primates.

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 4) 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. 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 5), 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 6) 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. 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.

2. Purpose and Use of Information Collection

Under the 42 CFR 71.53, CDC collects information pertaining to imported nonhuman primates. This information enables CDC to evaluate compliance with pre-arrival of shipment notification requirements, investigate the number and species of imported nonhuman primates, and to determine if adequate measures being taken for the prevention of exposure to persons and animals during importation.

The items of information collected from importers include the following:

- Names and contact information of importers, brokers, and transporters (42 C.F.R. 71.53 (g), 42 C.F.R. 71.53 (n))
- Standard operating procedures for handling non-human primates (42 C.F.R. 71.53 (g))
- Description of imported non-human primates (42 C.F.R. 71.53 (n))
- Statements indicating the purpose of importation (42 C.F.R. 71.53 (g))
- Health certificates, shipping documents, and non-human primate health records (42 C.F.R. 71.53(l)(3)

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 (Attachment 7). The form for filovirus testing is submitted electronically (Attachment 8). 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.

CDC also recently published in the Federal Register guidance for using the Document Image System (DIS) within the Automated Commercials Environment for importers of NHPs. This notice is available here: https://www.federalregister.gov/documents/2016/12/30/2016-31750/electronic-filing-of-certain-import-data-into-the-document-image-system-through-the-automated

The following collections may be submitted via DIS:

1) **Recordkeeping and reporting requirements for importing NHPs: Notification of shipment arrival 71.53(n) (no form)**
   Importers may submit notification of shipment arrival via DIS. In the event that importers/filers choose to use ITDS/ACE to document the importation of nonhuman primates or nonhuman primate products, the information requested of the importers/filers in DIS is the email notification message generated by CDC's Quarantine Activity Reporting System (QARS) when a registered importer notifies CDC of an incoming nonhuman primate shipment.
2) **Documentation of Non-infectiousness 71.53(t)**
   Importers may submit documentation under this collection via DIS.

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. A 60 day Federal Register Notice was published on March 8, 2017, Vol. 82, No. 44, page 12962. One non-substantive public comment was received (Attachment 2B). A standard response was sent.

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. Protection of the Privacy and Confidentiality of Information Provided by 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.

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.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

The protocols and tools used to conduct this information collection request have been reviewed and approved by NCEZID's Human Subjects Advisor, who determined that this data collection does not

meet the definition of research under 45 CFR 46.102(d). IRB review is not required (Attachment 9 CDC Nonresearch Determination Letter).

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 Requirements for Importers of Nonhuman Primates final rule requires importers to re-register every two years. This means that only half of the 23 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. The only information collections in the table below that include forms are CDC 75.10A Application for Registration as an Importer of Nonhuman Primates (both new and re-registration) and 71.53 (v) Form: Filovirus Diagnostic Specimen Submission Form for Non-human Primate Materials. The other information collections refer to regulatory provisions within 42 CFR 71.53 (Attachment 3).

- CDC estimates one new applicant for CDC registration/year will need to make NEW CDC registration (10 minutes).
- 23 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.
- 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.
- 23 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.
- 24 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.
- 24 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 100 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) (Attachment 7)	1	1	10/60	1
Nonhuman Primate Importer	CDC 75.10A Application for Registration as an Importer of Nonhuman Primates (Re-Registration) (Attachment 7)	12	1	10/60	2
Nonhuman Primate Importer	71.53(g)(1)(iii) and (h) Documentation and Standard Operating Procedures (no form) (New Importer) (Attachment 3)	1	1	10	10
Nonhuman Primate Importer	71.53(g)(1)(iii) and (h) Documentation and Standard Operating Procedures (no form) (Registered Importer) (Attachment 3)	12	1	30/60	6
Nonhuman Primate Importer	Recordkeeping and reporting requirements for importing NHPs: Notification of	24	6	15/60	36

	shipment arrival 71.53(n) (no form) (Attachment 3)				
Nonhuman Primate Importer	Quarantine release 71.53(l)(no form) (Attachment 3)	24	6	15/60	36
Nonhuman Primate Importer	71.53 (v) Form: Filovirus Diagnostic Specimen Submission Form for Non-human Primate Materials (Attachment 8)	10	10	20/60	33
Importer/Filer	CDC Partner Government Agency Message Set for Importing Live Nonhuman Primates (Attachment 10)	150	1	15/60	38
Importer/Filer	CDC Partner Government Agency Message Set for Importing Nonhuman Primate Products (Attachment 11)	2280	1	15/60	570
Importer/Filer	Documentation of Non-infectiousness 71.53(t) (Attachment 3)	2280	1	5/60	190
Total					922

B. The estimated total cost to the public is $24,118. 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 veterinarians/facility directors (http://www.bls.gov/oes/current/oes291131.htm) 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 is used for the hourly cost.

- The effort was apportioned by using the 75% percentile pay for vets (to account for the higher pay rate of the facilitate directors) with 75% of the respondent burden, and 25% of the response burden as being performed by animal caretakers.
- The result of this estimate is $45.11 per hour, which we have rounded to $45 per hour in the table below.
- For importers/filers, the general public occupational category is used as no BLS category was available for importers/filers or a similar occupation. The average wage is $22.23 (00-0000 All Occupations. 00-0000 All Occupations: http://www.bls.gov/oes/current/oes_nat.htm#00-0000)

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) (Attachment 7)	1	$45	$45
Nonhuman Primate Importer	CDC 75.10A Application for Registration as an Importer of Nonhuman Primates (Re-Registration) (Attachment 7)	2	$45	$90
Nonhuman Primate Importer	71.53(g)(1)(iii) and (h) Documentation and Standard Operating Procedures (no form) (New Importer) (Attachment 3)	10	$45	$450
Nonhuman Primate Importer	71.53(g)(1)(iii) and (h) Documentation and Standard Operating	6	$45	$270

Type of Respondent	Form Name/CFR Reference	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
	Procedures (no form) (Registered Importer) (Attachment 3)			
Nonhuman Primate Importer	Recordkeeping and reporting requirements for importing NHPs: Notification of shipment arrival 71.53(n) (no form) (Attachment 3)	36	$45	$1,620
Nonhuman Primate Importer	Quarantine release 71.53(l)(no form) (Attachment 3)	36	$45	$1,620
Nonhuman Primate Importer	71.53 (v) Form: Filovirus Diagnostic Specimen Submission Form for Non-human Primate Materials (Attachment 8)	33	$45	$1,485
Importer/Filer	CDC Partner Government Agency Message Set for Importing Live Nonhuman Primates (Attachment 10)	38	$23.23	$883
Importer/Filer	CDC Partner Government Agency Message Set for Importing Nonhuman Primate Products (Attachment 11)	570	$23.23	$13,241
Importer/Filer	Documentation of Non-infectiousness 71.53(t) (Attachment 3)	190	$23.23	$4,414
Total				$24,118

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

The Centers for Disease Control and Prevention (CDC) is requesting approval for a set of adjustments to the previously approved burden total for this information collection. These requested adjustments, totaling 22 hours, include a reduction in burden in three of the information collections under this approval. The adjustments are as follows:

Adjustments:

- The number of registered nonhuman importers declined by one. This results in fewer burden hours as fewer respondents are required to submit NHP importation-related information to CDC on an annual basis.

- The number of filovirus samples sent to and processed by CDC was fewer than anticipated over the previous three years of approval under this control number. CDC has reduced the estimated burden accordingly.

- The decline in burden is a result of these factors, and not the result of any change in regulation or policy. Therefore, CDC is adjusting downward the number of burden hours for the following collections (See table below):
    - Recordkeeping and reporting requirements for importing NHPs: Notification of shipment arrival 71.53(n) (no form): Reduction of two hours
    - Quarantine release 71.53(l) (No form): Reduction of two hours
    - 71.53 (v): Form: Filovirus Diagnostic Specimen Submission Form for Non-human Primate Materials: Reduction of 17 hours
    - 71.53(g)(1)(iii) and (h) Documentation and Standard Operating Procedures (no form) (Registered Importer): Reduction of one hour

Table of adjustments

Burden	Previous Estimate	Revised Estimate
Recordkeeping and reporting requirements for importing NHPs: Notification of shipment arrival 71.53(n) (no form)	38	36
Quarantine release 71.53(l) (No form)	38	36
71.53 (v): Form: Filovirus Diagnostic Specimen Submission Form for Non-human Primate Materials	50	33
71.53(g)(1)(iii) and (h) Documentation and Standard Operating Procedures (no form) (Registered Importer)	7	6
Total change		22

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: 60 day Federal Register Notice

Attachment 2B: Public comment

Attachment 3: 42 CFR 71.53 Foreign Quarantine

Attachment 4: 55 FR 15210: Special Permit Procedure

Attachment 5: Establishment of User Fees for Filovirus Testing of Nonhuman Primate Liver Samples Final Rule

Attachment 6: Requirements for Importers of Nonhuman Primates Final Rule

Attachment 7: CDC 75.10A Application for Registration as an Importer of Nonhuman Primates

Attachment 8: Filovirus Diagnostic Specimen Submission Form for Non-human Primate Materials

Attachment 9: CDC Nonresearch Determination Letter

Attachment 10: CDC PGA Message Set Requested Data of Live Nonhuman Primates

Attachment 11: CDC PGA Message Set Requested Data of NHP products