Requirements for the Importation of Nonhuman Primates into the United States
(OMB Control No. 0920-0263)

Request for Revision of Currently Approved Data Collection
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Requirements for the Importation of Nonhuman Primates into the United States (OMB Control No. 0920-0263)

Request for Revision of Approved Data Collection (expiring 4/30/2016)

The Centers for Disease Control and Prevention (CDC) Division of Global Migration and Quarantine requests a revision for the currently approved information collection: Requirements for the Importation of Nonhuman Primates into the United States (OMB 0920-0263, expiring 4/30/2016). The proposed revisions reflect the requirements posed by the upcoming implementation of the International Trade Data System (ITDS) and the associated Automated Commercial Environment (ACE) software. The changes in law and program administration have resulted in CDC requesting a net increase in the estimated number of burden hours (see Section 12 A) included in this information collection request (ICR). The total number of additional hours requested for this information collection is 798 hours.

The proposed revisions are as follows:

Program Changes due to Statutory Requirements:
CDC is requesting the following changes based on the upcoming implementation of ITDS and ACE, which allows importers/filers to voluntarily submit data concerning CDC-regulated imports electronically to CBP for clearance. These estimates are based on operational observation by Quarantine Staff at US ports of entry.

- 150 submissions of CDC PGA Message Set importing Live Nonhuman Primates (NHP), resulting in 38 additional requested burden hours
- 2280 submissions of CDC PGA Message Set data for importations of Nonhuman Primate products, resulting in an additional 570 requested burden hours

The following change is a correction to clarify the public burden associated with providing the required statements and documentation that an NHP product has been rendered non-infectious.

- 2280 submissions of documentation indicating that Nonhuman Primate products have been rendered noninfectious, resulting in an additional 190 hours of requested burden. These submissions can be accomplished via the Document Imagining System (described below). CDC retains the right to collect these in hard copy.

The estimates provided in this information collection request assume that every commercial import of NHP covered by CDC's regulations will require a data entry using ITDS and ACE. However, CDC is maintaining its authority to collect hard copies of required documentation, as currently authorized by the Office of Management and Budget, because the use of ITDS/ACE will not be required for imports entering the United States until a later date. CDC will accept both hard copy and electronic filing of

import-related documentation until the use of ACE is required for cargo entering the United States.

No changes are proposed to the following information collections currently approved by OMB:

- CDC 75.10A Application for Registration as an Importer of Nonhuman Primates (New and Registered Importer) (3 hours of burden)
- 71.53(g)(1)(iii) and (h) Documentation and Standard Operating Procedures (no form) (New and Registered Importer) (17 hours of burden)
- Recordkeeping and reporting requirements for importing NHPs: Notification of shipment arrival 71.53(n) (no form) (38 hours of burden)
- Quarantine release 71.53(l) (No form) (58 hours of burden)
- 71.53 (v) Form: Filovirus Diagnostic Specimen Submission Form for Non-human Primate Materials (50 hours of burden)

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 April 30, 2016. This revision focuses on requesting authorization to collect information associated with imports and cargo that are required via the "single window" provided by ITDS and the ACE software. This information will be requested by CDC in an electronic format which is not currently approved under this ICR.

Section 361 of the Public Health Service Act (42 USC 264) (Attachment A1) 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) (Attachment A2) 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 (42 CFR 71.53 Requirements for importers of nonhuman primates).

The Public Health Service Act and the existing regulations governing quarantine activities (42 CFR 71) authorize quarantine officers and other personnel to inspect and undertake necessary control measures with respect to conveyances, persons, and shipments of animals and etiologic agents in order to protect the public's health. Other inspection agencies, such as Customs and Border Protection (CBP), assist quarantine officers in public health screening of persons, pets, and other importations of public health importance and make referrals to quarantine station staff when indicated. 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.

The SAFE Port Act of 2006 (Attachment A3) requires that all agencies that require documentation for clearing or licensing the importation and exportation of cargo participate in ITDS. ACE is the software portal for ITDS and will ultimately become the single window through which the international trade community will electronically provide all information needed by federal agencies for the import and export of cargo.

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) (Attachment A4) and 49 CFR §1520.11(b) (Attachment A5), which permit federal employees with a need to know to have access to this data. As a government agency that requires documentation from an importer/filer in order for CBP to process and clear an import into the United States, CDC is submitting this revision to obtain authority to request certain electronic information from importers/filers on specific types of animals and cargo over which CDC has authority, specifically those found in 42 CFR Part 71.

The regulations found at 42 CFR 71 that are pertinent to this revision include the following:

- 42 CFR 71.53 Requirements for the importers of nonhuman primates

1.1 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 and nonhuman primate products 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.

Concerning this revision, ITDS is intended to provide an electronic “single-window” for reporting imports and exports to the government. Currently, traders must make redundant reports to multiple agencies (often on paper). When completed, ITDS will allow importers/filers to make a single electronic report, and the relevant data will be distributed to the appropriate agencies. Costs will be reduced for business and government. Agencies will obtain data more quickly through electronic filings, and with automated processing, be able to process cargo more expeditiously, and be better able to identify unsafe, dangerous, or prohibited shipments. The associated ACE Secure Data Portal software offers approved CDC staff near real-time review of Customs and Border Protection entry, entry summary and manifest data accessible via the Reports tab, as well as other information to which the user may be granted access, as appropriate.

In the even that importers/filers choose to use ITDS/ACE to import nonhuman primates or nonhuman primate products, CDC will request that specifically constructed PGA Message Sets be submitted to CBP and the ITDS/ACE system. All import specific data will be submitted into CBP's ITDS/ACE system by the importer/filer. This information includes that documentation or forms submitted in the Document Imaging System (DIS), a system that is available to store and transmit scanned images of relevant documents, e.g documentation related to rendering nonhuman primate products noninfectious. The following CDC PGA Message Sets will be available to importers/filers to submit when importing a CDC-regulated import:

- CDC Requested Data on Regulated Imports: Live Nonhuman Primates (Attachment E)
- CDC Requested Data on Regulated Imports: Nonhuman Primate Products (Attachment F)

Items of Information to be Collected

Data collected from importers who choose to import nonhuman primates and nonhuman primate products 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.

The requested revision to this information collection involves the addition of electronic data related to the regulated animals and animal products included in Part 71 via CDC PGA Message Sets. 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 the CDC PGA Message Sets includes the number, description, intended use, identification of holding facilities, and measures taken to reduce the risk of zoonotic transmission of disease. This information is limited to that required to identify the type of import, i.e. nonhuman primate and to determine if all requirements for entry have been met, i.e. permit or statement of non-infectiousness. A portion of this information collected is composed of Intended Use Codes, such as For Exhibition or For Research.

Use of ITDS/ACE and relevant descriptive data will enable CBP, with CDC consultation, to clear or release an import much faster than with previous paper-based submissions.

No changes are proposed to the following collections currently approved by OMB under this information request:

- CDC 75.10A Application for Registration as an Importer of Nonhuman Primates (New and Registered Importer) (3 hours of burden)
- 71.53(g)(1)(iii) and (h) Documentation and Standard Operating Procedures (no form) (New and Registered Importer) (17 hours of burden)
- Recordkeeping and reporting requirements for importing NHPs: Notification of shipment arrival 71.53(n) (no form) (38 hours of burden)
- Quarantine release 71.53(l) (No form) (58 hours of burden)

- 71.53 (v) Form: Filovirus Diagnostic Specimen Submission Form for Non-human Primate Materials (50 hours of burden)

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.

2.1 Privacy Impact Assessment:

1. The information collected as outlined in this request will become part of CDC Privacy Act System of Records (SORN) 09-20-0171, "Quarantine and Traveler-Related Activities, Including Records for Contact Tracing, Investigation, and Notification under 42 CFR Parts 70 and 71". CDC is in the process of updating this SORN to include importers.

Information 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. 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.

In the event that an import requires enhanced evaluation for public health reasons, some data may be extracted from CDC PGA Message Sets within ITDS/ACE and included in reports in Quarantine Activity Reporting System (QARS). Only data extracted from CDC PGA Message Sets will be entered into QARS.

3. Use of Improved Information Technology and Burden Reduction

Concerning this revision, rregistered importers/filers will have the option of submitting import information to the ITDS/ACE single window to send data to Customs and Border Protection (CBP). This electronic data system is intended to make importation quicker and more efficient across the government. Use of the information technology made available by ITDS/ACE will enable CDC to reduce the time to review import information and release imports. Registered importers/filers have the option to interface with ITDS/ACE using customizable, proprietary software, which will further enable their ability to enter data quickly into ITDS/ACE and speed the process of data submission for CBP and CDC to review. This has the potential to reduce burden on the importers/filers when ITDS/ACE is used.

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 collection of information primarily does not impact small business or other small entities. For those that will be impacted, CDC has reduced the burden imposed by CDC's PGA Message Sets to be the minimum necessary in order to meet its regulatory responsibilities.

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 or nonhuman primate products. 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. Further reduction of required recordkeeping or reporting would prevent CDC from meeting it legislative mandate and could therefore endanger the public's health. There are no legal obstacles to reduce 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 proprietary portions of applications publicly when discussing technical issues concerning 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 notice detailing CDC's use of the ACE single window with regard to the importation activities described in the current information collection request was published in the Federal Register on Tuesday, March 18, 2014, Vol. 79, 15127- 15129. (Attachment B). No comments were received.

B. Concerning this revision, CDC collaborated with CBP on the development of the data sharing and collection process used to develop the PGA message sets for each import regulated by CDC. Since the passing of the SAFE Port Act, CDC has been actively involved with the development of the ACE software. CDC has worked directly with CBP as well as with other federal agencies, through workgroups, to account for foreseeable regulated importation and the data necessary to make a release decision. In order to reduce costs and to streamline the data input that will be necessary, CDC will leverage the PGA Message Set instead of developing its own electronic system.

9. Explanation of Any Payment or Gift to Respondents

No monetary incentives or gifts are provided to respondents. Respondents must comply with the permit requirements to import nonhuman primates into the United States or importation will not be permitted.

10. Assurance of Confidentiality Provided to Respondents
This submission has been reviewed by the Information Collection Review Office, and it has been determined that the Privacy Act does apply to some aspects of this information collection request. 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. This submission has also been reviewed by the CDC Information Collection Review Office (ICRO).

Personally identifiable information provided by importers are limited. 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.

Information collected from ITDS/ACE in the form of CDC PGA Message Sets may be entered into the Quarantine Activity Reporting System (QARS), a secure computer system, for analysis. Data and source documents will be retained until the event prompting the collection of data has concluded in accordance with CDC's records retention schedule. Electronic media will be protected by adequate physical, administrative, and procedural safeguards to ensure the security of the data. Access will be restricted to agency employees with a bona fide "need to know" in order to carry out the duties of their positions or to accomplish the purposes for which the data were collected. When information is deleted, a special "certified" process will be used to completely overwrite tapes on the mainframe or overwriting (not merely deleting) microcomputer files. Source documents, printouts and thumb drives will be safeguarded by storing them in locked cabinets in locked offices when not in use.

<u>IRB Approval</u>
IRB approval is not required for this information collection.

<u>Privacy Impact Assessment Information</u>
1. Importers of live nonhuman primates 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. Use of the ITDS/ACE system is voluntary until a later date. CDC intends to accept hard copies until ACE/ITDS is mandatory, at which time any changes will be submitted for review and approval.

2. Any importer who intends to import nonhuman primates into the United States must comply with the permit, notification, documentation, and TB and filovirus testing requirements. By requesting the permit, a potential importer gives consent to this information collection and is aware of the reason for submitting the required documentation.

   Importers/filers wishing to import nonhuman primate products may complete the PGA message set information contained within ITDS/ACE in order for shipments to be reviewed by CBP, with consultation from CDC, for clearance. Consent for this

information will be obtained prior to submission through ITDS/ACE. CDC has no plans for sharing the information submitted for the permit or obtained for the importation of nonhuman primate products. Importers/filers wishing to import nonhuman primate products must provide documentation stating that the product has been rendered non-infectious.

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.

4. Parts of this data collection are subject to the Privacy Act. The existing applicable Systems of Records Notice for this revision is 09-20-0171.

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

The current approved respondent burden is 146 hours. Respondents remain registered importers (commercial or not-for-profit entities) of nonhuman primates and nonhuman primate products who seek approval from CDC for importation. The burden imposed by the registration, permit application, notification, documentation, and disease reporting requirements is based on the estimated amount of time needed to perform the requirement, multiplied by the number of responses. Figures are based on estimates from Quarantine Staff activity and recordkeeping at ports of entry. No changes are proposed to the estimates for burden under:

- CDC 75.10A Application for Registration as an Importer of Nonhuman Primates (New and Registered Importer) (3 hours of burden)
- 71.53(g)(1)(iii) and (h) Documentation and Standard Operating Procedures (no form) (New and Registered Importer) (17 hours of burden)
- Recordkeeping and reporting requirements for importing NHPs: Notification of shipment arrival 71.53(n) (no form) (38 hours of burden)
- Quarantine release 71.53(l) (No form) (58 hours of burden)
- 71.53 (v) Form: Filovirus Diagnostic Specimen Submission Form for Non-human Primate Materials (50 hours of burden)

The revision concerns additional information collection pertaining to the importation of live nonhuman primates and nonhuman primate products as part of the implementation of ITDS/ACE. CDC estimates the following burden associated with these activities:

- CDC estimates there will be 150 submissions of the CDC Partner Government Agency Message Set for the Importation of Live Nonhuman Primates. Each

submission will take approximately 15 minutes, for a total of 6 hours of respondent burden.

- CDC estimates there will be 2280 submissions of the CDC Partner Government Agency Message Set for the Importation of Nonhuman Primate Products. Each submission will take approximately 15 minutes, for a total of 570 hours of respondent burden.
- CDC estimates there will be 2280 submissions of the required documentation to indicate non-infectiousness, the same number as submissions of nonhuman primate products. Each submission will take approximately 5 minutes, for a total of 190 hours of respondent burden.

The total additional burden is an estimated 798 hours. The new requested burden total is 944 hours.

12 A. 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 form) (New Importer)	1	1	10	10
Nonhuman Primate Importer	71.53(g)(1)(iii) and (h) Documentation and Standard	12	1	30/60	7

	Operating Procedures (no form) (Registered Importer)				
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
Importer/Filer	CDC Partner Government Agency Message Set for Importing Live Nonhuman Primates	150	1	15/60	38
Importer/Filer	CDC Partner Government Agency Message Set for Importing Nonhuman Primate Products	2280	1	15/60	570
Importer/Filer	Documentation of Non-infectiousness	2280	1	5/60	190

	71.53(t)				
Total					944

12 B. The currently approved cost to the respondents is $5699 per year. As a result of this revision, which enables the voluntary submission of PGA Message Sets to CBP and CDC for nonhuman primate and nonhuman primate products, the estimated total cost to the public is $23,553.

These estimates are based on experience with the information requirements associated with existing application and review processes, 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.
- 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 $22.01.(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)	1	$41.02	$41
Nonhuman Primate	CDC 75.10A Application for	2	$41.02	$82

Type of Respondent	Form Name/CFR Reference	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Importer	Registration as an Importer of Nonhuman Primates (Registered Importer)			
Nonhuman Primate Importer	71.53(g)(1)(iii) and (h) Documentation and Standard Operating Procedures (no form) (New Importer)	10	$41.02	$410
Nonhuman Primate Importer	71.53(g)(1)(iii) and (h) Documentation and Standard Operating Procedures (no form) (Registered Importer)	7	$41.02	$287
Nonhuman Primate Importer	Recordkeeping and reporting requirements for importing NHPs: Notification of shipment arrival 71.53(n) (no form)	38	$41.02	$1,559
Nonhuman Primate Importer	Quarantine release 71.53(l) (no form)	38	$41.02	$1,559
Nonhuman Primate Importer	71.53 (v) Form: Filovirus Diagnostic Specimen Submission Form for Non-human Primate Materials	50	$41.02	$2,051

Type of Respondent	Form Name/CFR Reference	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Importer/Filer	CDC Partner Government Agency Message Set for Importing Live Nonhuman Primates	38	$22.01	$836
Importer/Filer	CDC Partner Government Agency Message Set for Importing Nonhuman Primate products	570	$22.01	$12,546
Importer	Documentation of Non-infectiousness 71.53(t)	190	$22.01	$4,182
Total		179	$41	$23,553

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

There are no other costs to respondents or record keepers.

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

CDC estimates the cost of reviewing PGA message sets as a portion of annual time spent at work by individuals who specialize in CDC regulated imports. CDC uses this

estimation method as not every import will come to the attention of CDC, only those which require review to determine if a public health risk exists. The personnel costs are as follows:

Staff GS Level	Average annual salary of staff reviewing data	Percent of time spent on reviewing CDC PGA Message Set Data	Total Cost
GS-13	$71,674	100%	$71,674
GS-9	$41,563	50%	$20,782
Total			$92,456

Finally, there are system costs associated with the use and maintenance of QARS. These costs include the IT costs. These costs are as follows:

QARS System Costs	$218,172
Total	$218,172

The total estimated cost to the government for this information collection is $433,788 per year

15. Explanation for Program Changes or Adjustments

These requested adjustments and program changes are the result of the upcoming implementation of ITDS and the associated ACE software. The changes in law and program administration have resulted in a net increase in the estimated number of burden hours (see Section 12 A) requested in this information collection. The total number of additional hours requested for this information collection total 798 hours. The program changes are as follows:

Program Changes
CDC is requesting the following changes based on the upcoming implementation of ITDS and ACE, which allows NHP importers/filers to voluntarily submit data concerning CDC-regulated imports electronically to CBP for clearance. These estimates are based on operational observation by Quarantine Staff at US ports of entry.

- 150 submissions of CDC PGA Message Set importing Live Nonhuman Primates, resulting in 38 additional requested burden hours
- 2280 submissions of CDC PGA Message Set data for importations of Nonhuman Primate products, resulting in an additional 570 requested burden hours
- 2280 submissions of documentation indicating that Nonhuman Primate products have been rendered noninfectious, resulting in an additional 190 hours of requested burden. These submissions can be accomplished via the Document Imagining System. CDC retains the right to collect these in hard copy.

The following change is a correction to clarify the public burden associated with providing the required statements and documentation that an NHP product has been rendered non-infectious.

- 2280 submissions of documentation indicating that Nonhuman Primate products have been rendered noninfectious, resulting in an additional 190 hours of requested burden. These submissions can be accomplished via the Document Imagining System. CDC retains the right to collect these in hard copy.

The estimates provided in this information collection request assume that every commercial importer of NHP covered by CDC's regulations will file a data entry using ITDS and ACE. However, CDC is maintaining its authority to collect hard copies of required documentation, as currently authorized by the Office of Management and Budget, because the use of ITDS/ACE will not be required for imports entering the United States until a later date. CDC will accept both hard copy and electronic filing of import-related documentation until the use of ACE is required for cargo entering the United States.

No changes are proposed to the following information collections currently approved by OMB:

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- 71.53 (v) Form: Filovirus Diagnostic Specimen Submission Form for Non-human Primate Materials (50 hours of burden)

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. No exemption is requested

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

List of Attachments

Attachment A1: Section 361 Public Health Service Act (42 USC 264)
Attachment A2: 42 CFR 71 Foreign Quarantine
Attachment A3: SAFE Port Act of 2006
Attachment A4: 6 CFR part 29.8(b)
Attachment A5: 49 CFR part 1520.11(b)
Attachment B: 60 Day Federal Register Notice
Attachment C: CDC 75.10A Application for Registration as an Importer of Nonhuman Primates
Attachment D: Filovirus Diagnostic Specimen Submission Form for Nonhuman Primate Materials
Attachment E: CDC Requested Data of Regulated Imports: Live Nonhuman Primates
Attachment F: CDC Requested Data of Regulated Imports: Nonhuman Primate Products