Requirements for the Importation of Nonhuman Primates into the United States

Request for OMB approval of a Revision Information Collection with OMB Control No. 0920-0263 (Expiring 8/31/2020)

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Supporting Statement B

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B. Collection of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

Statistical methods do not apply to this data collection. No statistical methods are used in this data collection. The respondent universe is all animal importers who want to import nonhuman primates and nonhuman primate products into the United States.

Respondents must submit an application to become a registered importer of nonhuman primates. To obtain this registration, the importer must submit a written plan to the Director of CDC which specifies steps that will be taken to prevent exposure of persons and animals during the entire importation and quarantine process for the arriving non-human primates. This includes disease prevention procedures throughout the chain of custody of these nonhuman primates from embarkation in the country of origin to release from quarantine. Information such as species, origin, and intended use for primates, transit information, isolation and quarantine procedures, and procedures for tuberculosis and filovirus testing of quarantined nonhuman primates. CDC evaluates compliance with the standards and determines whether adequate measures being taken to prevent the exposure of persons and animals during importation, transportation, and quarantine.

CDC monitors at least one shipment of non-human primates to be assured that the newly registered importer is following the standard operating procedures specified in the registration permit package. Once CDC is assured that adequate disease control practices are being used by new registrants, the registration can be extended to cover the receipt of additional shipments under the same plan for a period of two years and may be renewed upon request.

Concerning this information collection, there will be no sampling of importers seeking to bring live nonhuman primates or nonhuman primate products.

2. Procedures for the Collection of Information

An entity that wants to import nonhuman primates must successfully complete the CDC registration process to be allowed to import nonhuman primates. To receive the registration, the importer must submit a written plan to the Director of CDC which specifies steps that will be taken to prevent exposure of persons and animals during the entire importation and quarantine process for the arriving nonhuman primates. This includes disease prevention procedures throughout the chain of custody of these primates

from embarkation in the country of origin to release from quarantine. Additional information includes species, origin, and intended use for primates, transit information, isolation and quarantine procedures, and procedures for tuberculosis and filovirus testing of quarantined animals. CDC evaluates compliance with the standards and determines whether adequate measures being taken to prevent the exposure of persons and animals during importation.

The timelines for submission of information to CDC are generally as follows:
1) An importer must submit a registration application (Attachment 7), which includes information that the importer maintains Documentation and Standard Operating Procedures for protecting public health throughout the importation process (Attachment 3).
2) An importer must provide a notice of arrival of the animals 7 days prior to shipping them to the United States, and provide notice to CDC within 48 hours of arrival at the quarantine facility (Attachment 3).
3) During travel and the 31-day quarantine period, the importer must provide notice to CDC if any illness developments among the NHPs (Attachment 3).
4) In the event that an Old World NHP dies or is euthanized for any reason other than trauma or unexpected adverse environmental conditions during quarantine, liver tissue for filovirus antigen by using the antigen-capture ELISA method must be submitted to a qualified laboratory for testing. Currently, these samples are send to CDC for analysis (Attachment 8).
6) Importers must notify CDC that the 31-day quarantine period has ended and that there have been no illnesses prior to releasing the NHP's from quarantine, and notify CDC of the intent to release the animals (Attachment 3).

Submission of information pertaining to the importation of nonhuman primate can be accomplished when individuals arrive at ports of entry and must be done so through the ITDS/ACE systems using the Document Imaging System. Notifications for arrival and of illnesses during quarantine are gnereally submitted via email to CDC/DGMQ's Zoonosis Team.

When CDC approves a new registrant, that registrant is provided with a temporary registration that covers the shipment, arrival, and subsequent quarantine of the nonhuman primates. CDC monitors at least one shipment of nonhuman primates to be assured that the provisions of a registrant's approved standard operating procedures are followed by a new registrant. Upon successful quarantine of the nonhuman primate shipment, CDC converts the temporary registration to full registration status. Registration is then extended to cover the receipt of additional shipments under the same plan for a period of two years. Registration may be renewed if the importer complies with all aspects of the provisions of initial registration.

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

If the importer does not comply with each part of the registration application, including required notification to CDC for arrival, quarantine release requests, documentation requirements, or submit to required testing procedures for tuberculosis or filoviruses, registration might be suspended.

Any individual, regardless of registration status, may import nonhuman primate products. These importers are required to provide documentation clearly indicating that nonhuman primate products have been rendered non-infectious or the products must be accompanied by a CDC Import Permit Program permit. Without either of these forms of documentation, the nonhuman primate products may not enter the United States.

4. Tests of Procedures or Methods to be Undertaken

The information pertaining to nonhuman primate shipments, documentation requirements, notifications to CDC, and tuberculosis and filovirus testing collected from the importers is defined by regulations and requirements set by CDC. Information collection forms and procedures have been refined based on this experience.

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

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