

including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov*, or call the Reports Clearance Office on (202) 690-6162. Written comments and recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above e-mail address within 30 days.

Proposed Project: Evaluation of SAMHSA Primary Care Behavioral Health Integration Grant Program. Emergency Information Collection Clearance Request—OMB No. 0990-NEW-Assistant Secretary for Planning and Evaluation .

Abstract: The Assistant Secretary for Planning and Evaluation (ASPE) and the Substance Abuse and Mental Health Administration are funding an independent evaluation of the Substance Abuse and Mental Health Administration/Center for Mental Health Services' (SAMHSA/CMHS) Primary Care Behavioral Health Integration (PBHCI) grant program. Four-year PBHCI grants were awarded to thirteen grantees on October 1, 2009. A second group of nine grants and a third group of up to 38 additional grants will be awarded prior to October 1, 2010. The purpose of the PBHCI grants is to improve the overall wellness and

physical health status of people with serious mental illnesses (SMI), including individuals with co-occurring substance use disorders, by supporting communities to coordinate and integrate primary care services into publicly funded community mental health and other community-based behavioral health settings. The information collected through the evaluation will assist SAMHSA in assessing whether integrated primary care services produce improvements in the physical and mental health of the SMI population receiving services from community-based behavioral health agencies.

ESTIMATED ANNUALIZED BURDEN TABLE

Form	Number of respondents	Number of responses per respondent	Average burden per response (hours)	Total annual burden (hours)
Client exam/survey (control group, 1st cohort)	900	1	45/60	675
Client service report	63	4	8.00	2,016
Quarterly reports	60	4	2.00	480
New TRAC indicators	60	200	0.08	960
Leadership	9	1	2.00	18
PH Providers	9	1	1.50	14
MH Providers	9	1	1.00	9
Care Coordinators	6	1	1.50	9
Site visit interview (1st cohort, control sites)	15	1	2.00	30
Total	1,131	4,211

Seleda M. Perryman,
Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day-11-0263]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. Alternatively, to obtain a copy of the data collection plans and instrument, call 404-639-5960 and send comments to Carol Walker, Acting CDC Reports Clearance Officer, 1600 Clifton Road NE., MS-D74, Atlanta, Georgia 30333;

comments may also be sent by e-mail to *omb@cdc.gov*.

Comments are invited on (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have a practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Requirements for a Special Permit to Import *Cynomolgus*, African Green, or Rhesus Monkeys into the United States (OMB Control No. 0920-0263 exp. 6/30/2011)—Extension—National Center for Emerging and Zoonotic Infectious Diseases, (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is requesting OMB approval to continue its data collection, "Requirements for a Special Permit to Import *Cynomolgus*, African Green, or Rhesus Monkeys into the United States", for another three years. This data collection is currently approved under OMB Control No. 0920-0263. There are no revisions proposed to the currently approved information collection request.

A registered importer must request a special permit to import *Cynomolgus*, African Green, or Rhesus monkeys. To receive a special permit to import nonhuman primates, 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.

Under the special permit arrangement, registered importers must submit a plan to CDC for importation and quarantine if they wish to import the specific monkeys covered. The plan must address disease prevention procedures to be carried out in every step of the chain of custody of such

monkeys, from embarkation in the country of origin to release from quarantine. Information such as species, origin and intended use for monkeys, transit information, isolation and quarantine procedures, and procedures for testing of quarantined animals is necessary for CDC to make public health decisions. This information enables CDC to evaluate compliance with the standards and to determine whether the measures being taken are adequate to prevent exposure of persons and

animals during importation. CDC will monitor at least 2 shipments to be assured that the provisions of a special permit plan are being followed by a new permit holder. CDC will assure that adequate disease control practices are being used by new permit holders before the special permit is extended to cover the receipt of additional shipments under the same plan for a period of 180 days, and may be renewed upon request. This extension eliminates the burden on importers to repeatedly

report identical information, requiring submission only of specific shipment itineraries and information on changes to the plan which require approval.

Respondents are businesses or not-for-profit organizations that import nonhuman primates. The burden represents full disclosure of information and itinerary/change information, respectively. There are no costs to respondents except for their time to complete the requisition process.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Instrument	Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden
Request for Special Permit	Businesses (limited permit)	5	2	30/60	5
Request for Special Permit	Businesses (extended permit)	1	3	10/60	0.5
Request for Special Permit	Organizations (limited permit)	3	2	30/60	3
Request for Special Permit	Organizations (extended permit)	12	2	10/60	4
Total	12.5

Dated: November 30, 2010.

Carol Walker,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0606]

Agency Information Collection Activities; Proposed Collection; Comment Request; Additional Listing Information for Medical Device Registration and Listing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting and recordkeeping burden requirements associated with additional listing information for medical device

registration and listing by non-electronic means.

DATES: Submit either electronic or written comments on the collection of information by February 7, 2011.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, Daniel.Gittleson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information,

including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Additional Listing Information for Medical Device Registration and Listing (OMB Control Number 0910-0387)—Extension

The Food and Drug Administration Amendments Act of 2007 (FDAAA), enacted September 27, 2007, requires that device establishment registrations and listings under 21 U.S.C. 360(p) (including the submission of updated information) be submitted to the Secretary of Health and Human Services (the Secretary) by electronic means,