DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–08–0263]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an e-mail to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–6974. Written comments should be received within 30 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)—Extension—National Center for Preparedness, Detection, and Control of Infectious Diseases (NCPDCID), 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. 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 commercial or not-for-profit importers of nonhuman primates. These businesses and organizations apply for limited and/or extended permits to import these 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. The annualized burden for this data collection is 20 hours.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Businesses (limited permit)	2	5	30/60
Businesses (extended permit)	3	5	10/60
Organizations (extended permit)	15	5	10/60

Dated: April 18, 2008.

Maryam I. Daneshvar,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–08–0337]

Agency Forms Undergoing Paperwork Reduction Act Review

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Proposed Project

National Blood Lead Surveillance System (OMB No. 0920–0337)—Extension—National Center for Environmental Health (NCEH), Coordinating Center for Environmental Health and Injury Prevention (CCEHIP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The National Center for Environmental Health requests an extension for data collection through the National Blood Lead Surveillance System to continue its effort to collect information related to lead exposure among children and adults. The purpose of this project is to support Childhood Lead Surveillance Systems and the Adult Blood Lead Epidemiology and Surveillance Program (ABLES) at the state and national levels. The objectives for continuing data collection with the use of these systems are three fold. First, we would like to use surveillance data

to estimate the extent of elevated blood-lead levels (BLLs) among children less than 6 years old. This is important because it will allow us to systematically track the management and follow-up of those children found to be poisoned with lead.

Our next objective for the continued use of this system is to examine potential sources of lead exposure. Although we've been successful in eliminating atmospheric lead with the use of unleaded gasoline and have continued to make strides in the elimination of household sources of lead commonly found in paint and dust, recent events have highlighted other potentially hidden sources of lead. This system will allow us to track the burden of such hidden sources and will help us eliminate such threats with the establishment of laws aimed at preventing the importation of such goods into our nation. The establishment of such laws will of course be a joint effort between several federal agencies; however, this surveillance system will help facilitate our efforts.

The final objective of this system is to facilitate the allocation of resources for lead poison prevention activities. The allocation of federal resources to State surveillance systems are based on reports of blood-lead tests from laboratories. Ideally, laboratories report results of all lead tests to the state health department. State health departments then send reports to CDC using de-identified data. It is from these reports that CDC is able to determine funding levels.

The use of both Childhood Lead Surveillance System and the ABLES Program will allow us to systematically track pockets of exposure to lead. It will also allow us to fully understand exposure potential and ways in which to prevent future sources of lead poisoning. Both systems are invaluable and will no doubt help us as we continue our stride in the elimination of lead poisoning in our nation.

There is no cost to respondents other than their time. The total estimated annualized burden hours are 656.

ESTIMATED ANNUALIZED BURDEN

Respondents	Number of respondents	Number of response per respondent	Average burden per response (in hrs.)	Total burden hours
State and Local Health Departments for Child Surveillance	42	4	2	336
State and Local Health Departments for Adult Surveillance	40	4	2	320
Total				656

Dated: April 18, 2008.

Maryam I. Daneshvar,

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–2008–D–0180]

Draft Guidance for Industry on Developing Coronary Drug Eluting Stents; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of a public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Coronary Drug-Eluting Stent (DES) Guidance Document Workshop.'' FDA is cosponsoring the workshop with the Advanced Medical Technology Association (AdvaMed). The purpose of the workshop is to discuss the draft guidance entitled ''Coronary Drug-Eluting Stents: Nonclinical and Clinical Studies'' announced in the **Federal Register** of March 27, 2008, and its companion document entitled ''Coronary Drug-Eluting Stents-Nonclinical and Clinical Studies (Companion Document)'' (the Companion Document). The workshop intends to solicit additional comments on the issues and questions presented in the draft guidance during the open comment period.

DATES: The public workshop will be held on April 29, 2008, from 8 a.m. to 6 p.m. Participants are encouraged to arrive early to ensure time for parking, security screening, and registration before the meeting. Security screening will begin at 7 a.m., and registration will begin at 7:30 a.m. Please preregister by April 22, 2008, according to the instructions in section I.C of this document.

ADDRESSES: The public conference will be held at the Food and Drug Administration, White Oak Campus, Bldg. 2, located at 10903 New Hampshire Ave., Silver Spring, MD 20993.

FOR FURTHER INFORMATION CONTACT: Ashley Boam, Center for Devices and Radiological Health, 9200 Corporate Blvd. (HFZ–400), Rockville, MD 20850, 240–276–3983 *ashley.boam@fda.hhs.gov* or Elizabeth Hillebrenner, Center for Devices and Radiological Health, 9200 Corporate Blvd. (HFZ–450), Rockville, MD, 20850, 240–276–4222, *elizabeth.hillebrenner@fda.hhs.gov*

SUPPLEMENTARY INFORMATION:

I. The Public Workshop

A. Why Are We Holding This Public Workshop?

The purpose of the workshop is to discuss the draft guidance announced in the **Federal Register** of March 27, 2008 (73 FR 16311), and any issues that it may raise, and to solicit additional input on the issues and questions presented in this draft guidance. In addition, the purpose of this workshop is to discuss the Companion Document.

B. What Are the Topics We Intend To Address at the Workshop?

We hope to discuss a large number of issues at the workshop, including, but not limited to:

- How to characterize the drug substance, including chemistry, nonclinical systemic and local tissue pharmacology and toxicology, and how to evaluate potential for and consequences of systemic clinical exposure.
- How to characterize the drug-device combination product, including the chemical/physical/mechanical properties of the DES, the nonclinical local vascular and regional myocardial toxicology, and the clinical performance of the drug-stent combination.
- Regulatory considerations that are unique to DES combination products.