DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Community Services Block Grant (CSBG) Program Model Plan Application.

OMB No.: 0970–0382.

Description: Sections 676 and 677 of the Community Services Block Grant Act require States, including the District of Columbia and the Commonwealth of Puerto Rico, Tribes, Tribal organizations and U.S. territories applying for Community Services Block Grant (CSBG) funds to submit an application and plan (Model Application Plan). The application plan must meet statutory requirements prior to being funded with CSBG funds. Applicants have the option to submit a detailed application annually or biannually. Entities that submit a biannual application must provide an abbreviated application the following year if substantial changes to the initial application will occur. OMB renewal is being sought.

Respondents: State Governments, including the District of Columbia and the Commonwealth of Puerto Rico, Tribal Governments, Tribal Organizations, and U.S. territories.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Model State CSBG Application	56	1	10	560
Model Indian Tribes & Tribal Organizations CSBG Application	30	1	10	300

Estimated Total Annual Burden Hours: 860.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments 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 practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) 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 automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012–27104 Filed 11–6–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Head Start Grant Application and Budget Instruments.

OMB No.: 0970–0207.

Description: The Office of Head Start is proposing to renew, without changes, the Head Start Grant Application and Budget Instrument, which standardizes the grant application information that is requested from all Head Start and Early Head Start grantees applying for continuation grants. The application and budget forms are available in a password-protected, web-based system. Completed applications can be transmitted electronically to Regional and Central Offices. The Administration for Children and Families believes that this application form makes the process of applying for Head Start program grants more efficient for applicants.

Respondents: Head Start and Early Head Start grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
HS grant and budget instrument	1,600	1	33	52,800

Estimated Total Annual Burden Hours: 52,800.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address:

infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments 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 practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) 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 automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012–27101 Filed 11–6–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 5 and 6, 2012, from 8 a.m. to 6 p.m.

Location: Holiday Inn, Grand Ballroom, 2 Montgomery Village Ave., Gaithersburg, MD. The hotel phone number is 301–948–8900.

Contact Person: Jamie Waterhouse, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993 301–796–3063, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On December 5, 2012, during session I, the committee will discuss and make recommendations regarding the 515(i) order issued by FDA on April 9, 2009 [Docket No. FDA–2009–M–0101], for the external counter-pulsating (ECP) devices, one of the remaining pre-Amendment Class III devices. These systems typically consist of a treatment table, pressure cuffs and a controller. They are intended to provide noninvasive circulatory support by applying external pressure to the lower extremities during diastole to increase coronary perfusion pressure, and releasing external pressure during systole to reduce left ventricular workload.

On March 9, 1979 (44 FR 13426), FDA published a proposed rule for classification of ECP devices as class III requiring premarket approval. The Cardiovascular Device Classification Panel (the Panel) recommended class III because the device is life supporting and potentially hazardous to life or health even when used properly. In addition, the Panel believed that sufficient information did not exist to determine the adequacy of general controls or to establish standards to provide a reasonable assurance of the safety and effectiveness of the device. Subsequent to the proposed rule, in 1980, FDA classified external counter-pulsating devices into class III after receiving no comments on the proposed rule (45 FR 7966, February 5, 1980). In 1987, FDA published a clarification by inserting language in the codified language stating that no effective date had been established for the requirement for premarket approval for ECP devices (52 FR 17737, May 11, 1987).

The discussion at the panel meeting will involve making recommendations regarding regulatory classification to either reconfirm to class III (subject to premarket approval application [PMA]) or reclassify to class I or class II (subject to premarket notification [510(k)]), as directed by section 515(i) of the Federal Food, Drug and Cosmetic Act.

On December 5, 2012, during session II, the committee will discuss and make recommendations regarding the 515(i) order issued by FDA on April 9, 2009 [Docket No. FDA–2009–M–0101], for Intra-aortic balloon and control systems, one of the remaining pre-Amendment Class III devices. Intra-aortic balloon pump (IABP) systems consist of an inflatable balloon and a console which inflates in synchronization with the cardiac cycle. During diastole, the balloon will inflate, creating a rise in pressure in the aorta, thus increasing blood flow to the coronary arteries and increasing myocardial oxygen supply. During systole, deflation of the balloon causes a fall in pressure in the aorta, which assists the left ventricle by reducing the pressure that needs to be generated to achieve ejection through the aortic valve.

On March 9, 1979 (44 FR 13369), FDA published a proposed rule for classification of IABP devices as class III requiring premarket approval. The Panel recommended class III because the device is life supporting and because the Panel believed that insufficient medical and scientific information existed to establish a standard to assure the safety and effectiveness of the device. The Panel also stated that controversy exists as to whether the device is beneficial in many situations in which it is used, and that it is difficult to use the device safely and effectively. Subsequent to the proposed rule, in 1980, FDA classified IABP devices into class III after receiving no comments on the proposed rule (45 FR 7939, February 5, 1980). In 1987, FDA published a clarification by inserting language in the codified language stating that no effective date had been established for the requirement for premarket approval for IABP devices (52 FR 17736, May 11, 1987).

The discussion at the panel meeting will involve making recommendations regarding regulatory classification to either reconfirm to class III (subject to premarket approval application [PMA]) or reclassify to class I or class II (subject to premarket notification [510(k)]), as directed by section 515(i) of the Federal Food, Drug and Cosmetic Act.

On December 6, 2012, the committee will discuss and make recommendations regarding the 515(i) order issued by FDA on April 9, 2009 [Docket No. FDA–2009–M–0101], for Nonroller-type cardiopulmonary bypass blood pumps, one of the remaining pre-Amendment Class III devices. A nonroller-type cardiopulmonary bypass blood pump is a device that uses a method other than revolving rollers to pump blood. There are two types of