

Public reporting burden for this collection is estimated to average 10 hours per response, including the time for reviewing instructions, gathering and maintaining the data needed and reviewing the collection of information.

An agency may not conduct or sponsor and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

F. Required Notification of the State Single Point of Contact

This program is covered under Executive Order 12372, Intergovernmental Review of Federal Programs, and 45 CFR part 100, Intergovernmental Review of Department of Health and Human Services Program and Activities. Under the Order, States may design their own processes for reviewing and commenting on proposed Federal assistance under covered programs.

All States and Territories except Alabama, Alaska, Arizona, Colorado, Connecticut, Hawaii, Idaho, Indiana, Kansas, Louisiana, Massachusetts, Minnesota, Montana, Nebraska, New Jersey, Ohio, Oklahoma, Oregon, Pennsylvania, South Dakota, Tennessee, Vermont, Virginia, Washington, Wyoming, and Palau have elected to participate in the Executive Order process and have established Single Points of Contact (SPOCs). Applicants from these twenty-six jurisdictions need take no action regarding E.O. 12372. Applicants for projects to be administered by Federally-recognized Indian Tribes are also exempt from the requirements of E.O. 12372.

All remaining jurisdictions participate in the Executive Order process and have established SPOCs. Applicants from participating jurisdictions should contact their SPOCs as soon as possible to alert them of the prospective applications and receive instructions. The applicant must submit all required materials, if any, to the SPOC and indicate the date of the submittal (or the date of contact if no submittal is required) on the Standard Form 424, item 16a. Under 45 CFR 100.8(a)(2), a SPOC has 60 days from the application deadline to comment on proposed new or competing continuation awards. Applicants must submit any required material to the SPOCs as soon as possible so that the Federal program office can obtain and review SPOC comments as part of the award process. A listing of the SPOC for each participating state and territory with contact and address information is available at <http://whitehouse.gov/omb/grants/spoc.html>.

Under 45 CFR 100.8(a)(2), a SPOC has 60 days from the application deadline to comment on proposed new or competing continuation awards.

SPOCs are encouraged to eliminate the submission of routine endorsements as official recommendations.

Additionally, SPOCs are requested to clearly differentiate between mere advisory comments and those official State process recommendations which may trigger the accommodate or explain rule.

When comments are submitted directly to ACF, they should be addressed to: William Wilson, ACYF/ Office of Grants Management, 330 C Street SW, Washington, DC 20447, Attn: Head Start Partnerships with Tribally Controlled Land Grant Colleges and Universities. A list of the Single Points of Contact for each State and Territory can be found on the Web site: <http://www.whitehouse.gov/omb/grants/spoc.html>.

Catalogue of Federal Domestic Assistance 93.600.

Dated: July 10, 2003.

Joan E. Ohl,

Commissioner, Administration on Children, Youth and Families.

Appendix A—List of Tribally Controlled Land Grant Colleges/ Universities

1999 Institutions (Expiring FY 2003)

1. College of Menominee Nation
2. Fort Peck Community College
3. Leech Lake Community College
4. Northwest Community College
5. Sitting Bull College
6. Stone Child Community College

2000 Institutions (Expiring FY 2003)

1. Bay Mills Community College
2. Blackfeet Community College
3. Dull Knife College
4. Ft. Belknap
5. Little Big Horn College
6. Oglala Lakota
7. SIPI College

2001 Institutions (Expiring FY 2006)

1. Fond du Lac Tribal and Community College
2. Salish Kootenai College
3. Sinte Glaska University

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Medical Devices Dispute Resolution 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: Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on scientific disputes between the Center for Devices and Radiological Health and sponsors, applicants, and manufacturers.

Date and Time: The meeting will be held on August 20, 2003, from 8 a.m. to 6 p.m.

Location: Bethesda Marriott, Congressional Ballroom, 5151 Pooks Hill Rd., Bethesda, MD.

Contact Person: Les Weinstein, Center for Devices and Radiological Health (HFZ-5), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-827-7991, FAX 301-827-2565, lsu@cdrh.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 10232. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote regarding a scientific dispute between the agency and CardioGenesis Corp., related to the approvability of a premarket approval application for the Axcis Percutaneous Myocardial Revascularization (PMR) for late stage medically refractory angina. Background information for the day's topic, including the attendee list, agenda, and questions for the committee, will be posted on the Internet at <http://www.fda.gov/cdrh/panel/index.html> one business day before the meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by August 13, 2003. Oral presentations from the public will be scheduled between approximately 8 a.m. and 8:30 a.m. on August 20, 2003.

Near the end of the committee deliberations, a 30-minute open public session will be conducted for interested persons to address issues specific to the dispute before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before August 13, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at 301-594-1283, ext. 113, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 11, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03-18350 Filed 7-18-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA)

publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)-443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: AIDS Drug Assistance Program (ADAP): ADAP Monthly Client Utilization and Program Expenditures Report (OMB No. 0915-0219)—Extension

The Division of Service Systems (DSS)/Health Resources and Services Administration (HRSA) collects aggregated information on the number of clients being served by ADAPs, monthly expenditures by State ADAPs, and the purchase price of HIV/AIDS medications. State AIDS Drug Assistance Program (ADAPs), funded under the Title II of the Ryan White Comprehensive AIDS Resource Emergency (CARE) Act, as amended (Part B of Title XXVI of the Public Health Service Act), are designed to provide low income, uninsured, and underinsured individuals with access to HIV/AIDS medication that prevent serious deterioration of health arising from HIV disease, including the prevention and treatment of opportunistic infections.

During the last several years, there has been an increasing need for pharmaceuticals among uninsured and underinsured low income individuals who are HIV positive or diagnosed with AIDS. Due to the increasing demand, DSS/HRSA recognizes the importance of program planning and budget forecasting in order to maximize resources, and proposed to extend the current data collection form to collect relevant client utilization data and

program expenditure information from State ADAPs. This data collection effort is designed to allow DSS/HRSA (the funding agency) to continue monitoring nationwide trends in program growth, client utilization, expenditures and to assess the capacity of State ADAPs to maintain client services for clients throughout the fiscal year. The form will improve DSS/HRSA's ability to track the prices of HIV/AIDS drugs in order to ensure that State ADAPs are receiving the best price possible, to identify emerging issues and technical assistance needs and to share information among State ADAPs. It will also assist Title II grantees, State ADAPs, DSS/HRSA staff and policy makers at both the Federal and State level to understand the level of client demand for medications and the resources needed to meet those needs.

This report will collect time-specific data for the number of enrolled clients, the number of new clients, and the number of utilizing clients, the level of funds expended, and the price of HIV/AIDS drugs. A text box is provided to allow State ADAPs to report significant changes to their program, such as projected budget shortfall, program restrictions, client waiting lists, a change in eligibility criteria, or formulary changes. On a quarterly basis, State ADAPs will report the purchase price paid on a select number of HIV pharmaceuticals dispensed by each program. DSS/HRSA will continue to compile summary reports that are distributed back to grantees and State ADAPs on a quarterly basis. The data collected is used to guide program planning, formulate budget recommendations, and monitor State ADAPs, especially monitoring the balance between an individual State ADAPs available resources against the client demand for medications. The burden estimates are as follows:

HRSA forms title II ADAP grantees	Number of respondents	Responses per respondent	Total responses	Hour per responses	Total burden hours
Client and Expenditures	54	12	648	0.75	486
Drug Pricing	54	4	216	0.75	162
Total	54		864		648