be submitted to the contact person listed below by August 16, 1996. All comments will be reviewed and, if applicable, incorporated into the final announcement to be published in the Federal Register in October.

For Further Information Contact: Mary Willingham, Division of HIV/AIDS Prevention, NCHSTP, CDC, M/S A24, 1600 Clifton Road, NE, Atlanta, Georgia 30303, telephone 404/639–0965.

Dated: July 10, 1996.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–17987 Filed 7–15–96; 8:45 am]

BILLING CODE 4163–18–M

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Head Start Program Information Report (PIR)

OMB No.: 0980–0017

Description: The Head Start Act requires that the Program Information Report (PIR) information is collected from Head Start grantees and delegate agencies. Data elements are primarily in the areas of management, class activity, health profile and home environment. Principal user of the data include local program management, ACF regional management, ACYF central office management, management of services to children with disabilities, and dissemination to other interested parties.

Respondents: Not-for-profit institutions, and State, Local or Tribal Govt.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
PIR	2,078	4	3.35	6,691

Estimated Total Annual Burden Hours: 6,691.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the Federal Register. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, N.W., Washington, D.C. 20503, Attn: Ms. Wendy Taylor.

Dated: July 9, 1996.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 96–17958 Filed 7–15–96; 8:45 am]

BILLING CODE 4184–01–M

Food and Drug Administration

[Docket No. 96M–0239]

Arrow International; Premarket Approval of the Model 3000 Constant Flow Inplantable Pump with Bolus Safety Valve

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Arrow International, Walpole, MA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Model 3000 Constant Flow Implantable Infusion Pump with Bolus Safety Valve. After reviewing the recommendation of the General Hospital and Personal Use Device Section of the General Medical Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of March 11, 1996, of the approval of the application.

DATES: Petitions for administrative review by August 15, 1996.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Richard E. Galgon, Center for Devices and Radiological Health (HFZ–420), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1287.

SUPPLEMENTARY INFORMATION: On September 18, 1990, Arrow International, Walpole, MA 02081, submitted to CDRH an application for premarket approval of the Model 3000 Constant Flow Implantable Infusion Pump with Bolus Safety Valve. The device is an implantable infusion pump and is indicated for the continuous regional intra-arterial delivery of 2'-deoxy-5-fluorouridine (FUDR), heparinized saline, normal saline, and bacteriostatic water.

On March 5, 1991, the General Hospital and Personal Use Device Section of the General Medical Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On March 11, 1996, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested

person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before August 15, 1996, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: June 21, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 96–17956 Filed 7–15–96; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Program Announcement, Proposed Project Requirements, Review Criteria, and Funding Preference for Regional Nursing Partnerships to Provide Continuing Education in Nursing Informatics for Faculty in Medically Underserved Communities

The Health Resources and Services Administration (HRSA) announces that applications will be accepted for fiscal year (FY) 1996 Cooperative Agreements for Regional Nursing Partnerships to Provide Continuing Education in Nursing Informatics for Faculty in Medically Underserved Communities. These cooperative agreements will be funded for one year under the Public Health Service Act, as amended by Nurse Education and Practice Improvement Amendments of 1992, Title II, Public Law 102–408, dated October 13, 1992, Section 820 (c), Continuing Education for Nurses in Medically Underserved Communities. It is anticipated that $280,000 will be available to support up to three competitive one-year awards.

Purpose

The purpose of the cooperative agreements is to support the formation of partnerships between recognized regional nursing organizations and nursing entities qualified to provide continuing education in nursing informatics for nursing faculty in schools located in, or preparing students to serve in, medically underserved communities. Nursing informatics is defined as the integration of nursing science, computer science, and information science applied to the identification, collection, analysis, and management of data for nursing education, practice, and research. Increasing the number of nurses in the workforce who are knowledgeable about nursing informatics, especially those practicing in underserved or rural communities, will enhance clinical proficiency and improve access to and quality of health care for increasing numbers in the population. For the purpose of these cooperative agreements, regional nursing organizations are those regionally based nursing organizations whose members must include schools of nursing in institutions of higher education located within the designated region, and whose members may also include health care agencies and other health care entities.

Applicants must establish and maintain effective partnerships to implement sound continuing education programs designed to meet the identified nursing faculty needs in nursing informatics. Continuing education program curricula must be based on regional assessments of undergraduate and graduate nursing faculty proficiency in computer technology and nursing informatics.

Eligibility and Proposed Funding Preference

Eligible applicants include public and non-profit entities. A funding preference is defined as the funding of a specific category or group of approved applications ahead of other categories or groups of approved applications in a discretionary program. It is proposed that a funding preference will be given to recognized regional nursing organizations who enter partnerships with nursing entities experienced in teaching nursing informatics. These entities may include, but are not limited to, schools of nursing. The partner providing the nursing informatics expertise must be located within the recognized regional nursing organization's designated region. It is highly unlikely that any applicant not meeting the funding preference will be supported under this cooperative agreement.

Proposed Project Requirements

1. Develop a formalized partnership between the regional nursing organization and nursing entities qualified to provide continuing education in nursing informatics.

2. Establish an Advisory Board to oversee the development, administration, and evaluation of the project. The Advisory Board must include at least one non-academically based nurse practicing in a medically underserved community.

3. Utilize an existing assessment of undergraduate and graduate nursing programs within the region to determine:

(a) The availability of computer-based systems;

(b) Faculty knowledge, skills, and abilities in the use of computer-based systems; and

(c) The ability of faculty to prepare students for practice in technologically advanced practice environments.

4. Based on analysis of the assessment in #3, develop and implement four regionally-based nursing informatics continuing education programs during the 1997 academic year. Each continuing education program must be designed to:

(a) Enhance faculty knowledge, skills, and abilities in nursing informatics in the areas of computer technology;