

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).

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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 Implantable 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