Dated: May 9, 2001.

Nancy Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 01–12373 Filed 5–15–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Program Announcement No. ACYF/HS 2001–07A]

Fiscal Year 2000 Discretionary Announcement for Head Start Family Worker Training and Credentialing Initiative; Availability of Funds and Request for Applications

AGENCY: Administration for Children, Youth, and Families, ACF, DHHS.

ACTION: Notice; Correction.

SUMMARY: This document contains a correction to the Notice that was published in the **Federal Register** on Thursday, May 3, 2001, Part II. On page 22294, first column (Item D), the August 1, 2001 closing date for the submission of applications is incorrect. The correct closing time and date for receipt of applications is 5 p.m. EDT on July 2, 2001.

FOR FURTHER INFORMATION CONTACT: The ACYF Operation Center at 1–800–351–2293 for referral to the appropriate contact person in ACYF for programmatic questions or send an e-mail to *hs@icgnet.com*

Dated: May 10, 2001.

James A. Harrell,

Acting Commissioner, Administration on Children, Youth and Families.

[FR Doc. 01–12283 Filed 5–15–01; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N-0050]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Premarket Approval of Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by June 15, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION:

I. Background

In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Premarket Approval of Medical Devices—21 CFR Part 814 (OMB Control No. 0910–0231)—Extension

Section 515 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(e)) sets forth the requirements for premarket approval of certain class III medical devices. Class III devices are either preamendments devices that have been classified into class III, postamendments devices that are not substantially equivalent to a preamendments device, or transitional devices. Class III devices are devices such as implants, life sustaining or life supporting devices, or devices which otherwise present a potentially unreasonable risk of illness or injury, or for which are of substantial importance in preventing impairment of human health. Most premarket approval applications (PMAs) are for postamendments class III devices.

Under section 515 of the act, an application must contain several pieces of information including full reports of all information concerning investigations showing whether the device is reasonably safe and effective. The application should also include a statement of components, ingredients, and properties and of the principle or principles of operation of such a device and should also include a full description of the methods used in, and the facilities and controls used for the manufacture and processing of the device; and labeling specimens.

The implementing regulations, contained in part 814 (21 CFR part 814), further specify the contents of a PMA for a class III medical device and the criteria FDA employs in approving, denying, or withdrawing approval of a PMA and supplements to PMAs. The regulation's purpose is to establish an efficient and thorough procedure for FDA's review of PMAs and supplements to PMAs for certain class III (premarket approval) medical devices. The regulations contained in part 814 facilitate the approval of PMAs and supplements to PMAs for devices that have been shown to be reasonably safe and effective and otherwise meet the statutory criteria for approval. The regulations also ensure the disapproval of PMAs and supplements to PMAs for devices that have not been shown to be reasonably safe and effective and that do not otherwise meet the statutory criteria for approval.

The Food and Drug Modernization Act of 1997 (FDAMA) (Public Law 105–115) was enacted on November 21, 1997, to implement revisions to the act by streamlining the process of bringing safe and effective drugs, medical devices, and other therapies to the U.S. market. Several provisions of this act affect the PMA process, such as section 515(d)(6) of the act. This section provided that PMA supplements were required for all device changes that affect safety and effectiveness of a device unless such changes are modifications to manufacturing procedures or method of manufacture. This type of manufacturing change requires a 30-day notice, or where FDA finds such notice inadequate, a 135-day PMA supplement.

To make the PMA process more efficient, FDA has in the past 3 years made changes to the PMA program based on comments received, has complied with changes to the program mandated by FDAMA and has worked towards completion of its PMA reinvention efforts.

Respondents to this information collection are persons filing a PMA application or a PMA supplement with FDA for approval of certain class III medical devices. Part 814 defines a person as any individual, partnership, corporation, association, scientific or academic establishment, government agency or organizational unit, or other legal entity. These respondents include entities meeting the definition of manufacturers such as manufacturers of commercial medical devices in distribution prior to May 28, 1976 (the enactment date of the Medical Device Amendments). Additionally, hospitals that reuse single use devices (SUDs) are