Type of respondents	Number. of respondents	Number. of responses per respondent	Average burden per response (in hours)	Total burden in hours
Morgantown community members	200	1	90/60	300
Forklift operators	200	1	90/60	300
Various occupational groups	400	1	90/60	600
Total	800	.....	.....	1,200

Dated: May 9, 2001.

Nancy Cheal,

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

[FR Doc. 01–12372 Filed 5–15–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY–30–01]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project

Survey of User Satisfaction with National Health Care Survey Data—New—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC). This Survey of User Satisfaction with National Health Care Survey Data is needed to provide current information on the use and usefulness of the variety of data products describing health care delivery systems in the United States. The National Health Care Survey comprises several component surveys: National Hospital Discharge Survey, National Nursing Home Survey, National Home and Hospice Care Survey, National Ambulatory Medical Care Survey, National Hospital Ambulatory Medical Care Survey and occasional other similar surveys when funded, such as the National Health Provider Inventory. Unlike other national surveys conducted by CDC National Center for Health Statistics, the National Health Care surveys address the health care delivery systems rather than the vital statistics, health status, health-related behavior, and access to care experienced by individuals and households who are consumers of the health care delivery systems. Between the years of 1968 and 1984, a number of surveys were conducted to learn more about National Center for Health Statistics (NCHS) data users and to assess the quality of data dissemination activities conducted by NCHS. Studies focusing solely on user satisfaction with National Health Care Survey data products have not been conducted since 1984. We need current specific information on how well our users' needs are being met, how to improve our data products, and how to serve current non-users of our data who are, nonetheless, potential users. Our data products consist mainly of published reports and web-published data sets including Data Highlights and E-Stats. Our published reports include Advance Data Reports, a newsletter-like summary of more detailed analyses to be published later, and Series Reports, which are in-depth analyses of specific topics addressed by our collected data. As the contractor for this project, CHPS Consulting will conduct a multi-mode survey using a web-based survey for those in the sample for whom an email address is available and a mail survey for those without an email address. Current users will be asked questions about what publications they use, how they use them, and their opinion of the timeliness, accessibility, format, and quality of the data publications. Non-users will be asked why they do not use our publications, their current sources of health care provider data, and how we improve data products to meet their needs. Our target population will include the following groups of persons: researchers, educators, health facility administrators, practitioners, and policymakers. Our goal for this survey is to obtain 600 returned surveys with an approximately equal number of returned surveys from users and non-users. The total annualized burden is 75 hours.

Respondents	Number of respondents	Number of responses per respondent	Avg. burden per response (in hrs.)
Users	300	1	10/60
Non-Users	300	1	5/60

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