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

also included in the definition of manufacturers. For the next 3 years, it is expected that FDA will receive four PMA applications from hospitals that remanufacture SUDs. This figure has been included in table 1 of this document as part of the reporting burden in § 814.15.

In the **Federal Register** of February 8, 2001 (66 FR 9582), the agency requested comments on the proposed collection of information. No comments were received.

The total estimated reporting and recordkeeping burden for this information collection is 107,321 hours. FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR section	No. of respondents	Annual rrequency per response	Total annual responses	Hours per response	Total hours
814.15, 814.20, and 814.37	62	1	62	837	51,894
814.39(f)	487	1	487	66	32,142
814.82	43	1	43	66	5,805
814.84	43	1	43	10	430
Section 201 (FDAMA)	10	1	10	10	100
Section 202 (FDAMA)	15	1	15	10	150
Section 205 (FDAMA)	8	1	8	50	400
Section 208 (FDAMA)	26	1	26	30	780
Section 209 (FDAMA)	8	1	8	40	320
Total					92,021

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR section	No. of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per recordkeeper	Total hours
814.82(a)(5) and (a)(6)	900	1	900	17	15,300

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The industry-wide burden estimate for PMAs is based on an FDA actual average fiscal year annual rate of receipt of 62 PMA original applications and 487 PMA supplements, using fiscal year 1996 through 2000 data.

The burden data for PMAs is based on data provided by manufacturers by device type and cost element in an earlier study. The specific burden elements for which FDA has data are as follows: (1) Clinical investigations: 67 percent of total burden estimate; (2) submission of additional data or information to FDA during a PMA review: 12 percent; (3) additional device development cost (e.g., testing): 10 percent; and (4) PMA and PMA supplement preparation and submissions, and development of manufacturing and controls data: 11 percent.

II. Paperwork Burden Estimate

The burden estimates were derived by consultation with FDA and industry personnel. FDA's estimates are based on actual data collected from industry over the past 3 years. An evaluation of the type and scope of information requested was also used to derive some time estimates. For example, disclosure information primarily requires time only to update and maintain existing manuals.

A. Reporting/Disclosure

The reporting burden can be broken out by certain sections of the PMA regulation: (1) § 814.15 *Research conducted outside the United States*; (2) § 814.20 *Application*; and (3) § 814.37 *PMA amendments and resubmitted PMA's*.

The majority of the burden—51,894 burden hours—is due to the above three requirements. Included in these three requirements are the conduct of laboratory and clinical trials as well as the analysis, review, and physical preparation of the PMA application. FDA estimates that 62 manufacturers (including hospital remanufacturers of single use devices) will be affected by these requirements based on actual average FDA receipt of new PMA applications in years 1996 through 2000. FDA's estimate of the hours per response (837) was derived through FDA's experience and consultation with industry and trade associations. Included in these three requirements are the conduct of laboratory and clinical trails as well as the analysis, review, and physical preparation of the PMA application. In addition, FDA has based its estimate on the results of an earlier study that these requirements account for the bulk of the burden identified by manufacturers.

1. § 814.39(f)—PMA Supplements: 32,142 Burden Hours

FDA believes that the amendments mandated by FDAMA for § 814.39(f), permitting the submission of the 30-day notices in lieu of regular PMA supplements, will result in an approximate 10 percent reduction in the total number of hours as compared to regular PMA supplements. As a result, FDA estimates that 32,142 hours of burden are needed to complete the requirements for regular PMA supplements.

2. § 814.82—Postapproval requirements: 5,805 Burden Hours

Postapproval requirements concern approved PMAs that were not reclassified and require a periodic report. In the last decade (1991 to 2000), the range of PMAs that fit this category averaged approximately 43 per year (70 percent of the 62 periodic submissions). Most approved PMAs have been subject to some postapproval study requirement. Approximately half of the average submitted PMAs (31) require associated postapproval studies (i.e., followup of patients used in clinical trials to support the PMA or additional preclinical information) that is labor-intensive to compile and complete, and the other PMAs require minimal information. Based on its experience

and on consultation with industry, FDA estimates that preparation of reports and information required by this section require 5,805 hours (135 hours per respondent).

3. § 814.84—Reports: 430 Burden Hours

Postapproval requirements described in § 814.82 (above) require a periodic report. FDA has determined respondents meeting the criteria of § 814.84 will submit reports on a periodic basis. As stated previously, the range of PMAs fitting this category averaged approximately 43 per year. These reports have minimal information requirements. FDA estimates that respondents will construct their report and meet their requirements in approximately 10 hours. This estimate is based on FDA's experience and on consultation with industry. FDA estimates that the periodic reporting required by this section take 430 hours.

The total hours for statutory burden is 1,750. This burden estimate was based on actual real FDA data tracked from January 1, 1998, to the present, and an estimate was derived to forecast future expectations with regard to this statutory data.

B. Recordkeeping

The recordkeeping burden in this section involves the maintenance of records used to trace patients and the organization and indexing of records into identifiable files to ensure the device's continued safety and effectiveness. These records would be required only of those manufacturers who have an approved PMA and who had original clinical research in support of that PMA. For a typical year's submissions, 70 percent of the PMAs are eventually approved and 75 percent of those have original clinical trial data. Therefore, approximately 43 PMAs a year (62 annual submissions times 70 percent) would be subject to these requirements. Also, because the requirements apply to all active PMAs, all holders of active PMA applications must maintain these records. PMAs have been required since 1976, and there are 900 active PMAs that could be subject to these requirements, based on actual FDA data. Each study has approximately 200 subjects, and, at an average of 5 minutes per subject, there is a total burden per study of 1,000 minutes, or 17 hours. The aggregate burden for all 900 holders of approved original PMAs, therefore, is 15,300 hours (900 approved PMAs with clinical data x 17 hours per PMA).

The applicant determines which records should be maintained during product development to document and/or substantiate the device's safety and effectiveness. Records required by the current good manufacturing practices for medical devices regulation (21 CFR part 820) may be relevant to a PMA review and may be submitted as part of an application. In individual instances, records may be required as conditions to approval to ensure the device's continuing safety and effectiveness.

Dated: May 11, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–12277 Filed 5–15–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00E–1412]

Determination of Regulatory Review Period for Purposes of Patent Extension; Uvasorb HA88

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Uvasorb HA88 and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that food additive.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Regulatory Policy Staff (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5645.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years as long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For food additives, the testing phase begins when a major health or environmental effects test involving the food additive begins and runs until the approval phase begins. The approval phase starts with the initial submission of a petition requesting the issuance of a regulation for use of the food additive and continues until FDA grants permission to market the food additive product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted, as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a food additive will include all of the testing phase and approval phase as specified in 35 U.S.C. section 156(g)(2)(B).

FDA recently approved for marketing the food additive Uvasorb HA88. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Uvasorb HA88 (U.S. Patent No. 4,477,615) from 3V Partecipazioni Industriali S.p.A., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated August 4, 2000, FDA advised the Patent and Trademark Office that this food additive had undergone a regulatory review period and that the approval of Uvasorb HA88 represented the first permitted commercial marketing or use of the product. Subsequently, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Uvasorb HA88 is 3,482 days. Of this time, 684 days occurred during the testing phase of the regulatory review period, and 2,798 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a major health or environmental effects test (test) involving this food additive additive product was begun*: November 2, 1989. FDA has verified the applicant's claim that the test was begun on November 2, 1989.

2. *The date the petition requesting the issuance of a regulation for use of the additive (petition) was initially*