DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0066]

Agency Emergency Processing Under OMB Review; Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information will be used by FDA to publish the criteria FDA intends to use to accredit third parties to conduct inspections of eligible manufacturers of class II and class III medical devices.

DATES: Fax written comments on the information collection provisions by May 28, 2003. FDA is requesting approval of this emergency processing by June 12, 2003, under the PRA of 1995 to implement the statutory provision under section 201 of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA).

ADDRESSES: Submit written comments on the collection of information to OMB. OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be electronically mailed to sshapiro@omb.eop.gov or faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Stuart Shapiro, Desk Officer for FDA, FAX: 202–395–6974. All comments should be identified with the docket number found in brackets in the heading of this document.

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

SUPPLEMENTARY INFORMATION: FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j) and 5 CFR 1320.13). This information is needed immediately so that the agency can publish the criteria required to implement an Inspection by Accredited Persons Program to accredit persons that wish to conduct inspections of eligible manufacturers of class II and class III medical devices. FDA is requesting this emergency processing to implement the statutory provision under section 201 of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) directing FDA to publish criteria for accrediting third parties within 180 days of enactment of MDUFMA. In addition, FDA must accredit persons under the published criteria no later than 1 year after enactment of MDUFMA. MDUFMA was signed into law on October 26, 2002. The use of normal clearance procedure would likely result in the prevention or disruption of this collection of information. Therefore, FDA has requested approval of emergency processing of this proposed collection of information by June 12, 2003.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Inspection by Accredited Persons Program Under MDUFMA

MDUFMA, Public Law 107–250, amends section 704 (21 U.S.C. 374) of the Federal Food, Drug and Cosmetic Act. MDUFMA was signed into law on October 26, 2002.

New section 704(g)(1) of the act (21 U.S.C. 374(g)(1)) directs FDA to accredit persons to inspect eligible manufacturers of class II and class III medical devices in lieu of an FDA inspection. Under section 704(g)(2) (21 U.S.C. 374(g)(2)) of the act, FDA must publish, within 180 days of enactment of MDUFMA, criteria for the accreditation of third parties to conduct inspections of eligible manufacturers of class II and class III medical devices. Within 60 days of receiving a request for accreditation, FDA must inform the requestor whether the request for accreditation is adequate for review. Under section 704(g)(4) of the act (21 U.S.C. 374(g)(4)), FDA must publish, on the Internet, a complete list of accredited persons and the activities for which they are accredited. These sections of the act will enable FDA to implement an ''Inspection by Accredited Persons Program'' under MDUFMA.

Participation in the program is voluntary. Manufacturers may continue to have FDA perform inspections or, if eligible, they may utilize an accredited person. FDA will serve as the accreditation body. FDA will began accepting applications immediately following approval by OMB of the proposed collection of information. Because the statute requires the agency to make accreditation decisions no later than 1 year after MDUFMA's enactment (October 26, 2003), FDA intends to stop accepting applications on August 25, 2003.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a document announcing the criteria it will use to accredit persons to inspect eligible device manufacturers and the availability of a guidance entitled ''Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria: Guidance for Industry, FDA Staff, and Third Parties.'' The guidance further describes the criteria FDA will use to accredit persons that wish to conduct inspections of eligible manufacturers of class II and class III medical devices. The guidance also addresses the format and content of accreditation applications and the evaluation process FDA will use in qualifying firms to participate in this program.

Respondents to the proposed collection of information will likely be businesses or other for-profit organizations.

FDA estimates the burden of this information collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Item	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Request for Accreditation (1st Year)	25	1	25	80	2000
Request for Accreditation (2nd Year)	10	1	10	15	150
Request for Accreditation (3rd Year)	5	1	5	80	400
Total Hours					2,550

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

FDA based these estimates on conversations with industry, trade association representatives, and internal FDA estimates. Our expectation is that 25 bodies will apply and meet the minimum standard for being accredited. Under MDUFMA, we can only accredit 15 persons during the first year. We expect that the lowest ranking 10 (the ones not accredited), will reapply the following year and will submit an updated application. Five new applicants may apply the third year. Once an organization is accredited, it will not be required to reapply.

Dated: April 23, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00E–1403]

Determination of Regulatory Review Period for Purposes of Patent Extension; PREVNAR

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for PREVNAR 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 Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human biological product.

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. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3460.

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 so 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 human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director 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 human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human biologic product PREVNAR. PREVNAR is indicated for immunization of infants 2, 4, 6, and 12 to 15 months of age to prevent invasive pneumococcal disease. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for PREVNAR (U.S. Patent No. 5,360,897) from the University of Rochester through American Home Products, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 30, 2002, FDA advised the Patent and Trademark Office that this human biologic product had undergone a regulatory review period and that the approval of PREVNAR represented the first permitted commercial marketing or use of the product. Shortly thereafter, 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 PREVNAR is 1,910 days. Of this time, 1,648 days occurred during the testing phase of the regulatory review period, while 262 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: November 27, 1994. The applicant claims November 25, 1994, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 27, 1994, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act*: June 1, 1999. FDA has verified the applicant's claim that the product license application (PLA) for PREVNAR (PLA 99–0279) was initially submitted on June 1, 1999.

3. *The date the application was approved*: February 17, 2000. FDA has verified the applicant's claim that PLA 99–0279 was approved on February 17, 2000.