document identifier, to *Paperwork@hcfa.gov,* or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: March 20, 2003.

Dawn Willinghan,

Acting, Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances.

[FR Doc. 03–7305 Filed 3–26–03; 8:45 am]

BILLING CODE 4210–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–901 and CMS–3070]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare and Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA)), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Qualification Application: Medicare+Choice Application for HMOs, PPOs, and State Licensed PSOs; Medicare+Choice Application for Federally Waived PSOs; Medicare+Choice Application for Medicare Savings Account Entitities; Medicare+Choice Application for Private Fee-for-Service Plans.; *Form No.:* CMS–901 (OMB# 0938–0470); *Use:* Prepaid health plans must meet certain regulatory requirements to be federally qualified health maintenance organizations or to enter into a contract with CMS to provide health benefits to Medicare beneficiaries. The application is the collection form to obtain the information from a health plan that will allow CMS staff to determine compliance with the regulations.; *Frequency:* Other: One-time submission.; *Affected Public:* Business or other for-profit, Not-for-profit institutions, State, Local or Tribal Government; *Number of Respondents:* 55; *Total Annual Responses:* 55; *Total Annual Hours:* 5,500.

2. *Type of Information Collection Request:* Extension of a previously approved collection; *Title of Information Collection:* Intermediate Care Facility for the Mentally Retarded or Persons with Related Conditions ICF/MR Survey Report Form (3070G–I) and Supporting Regulations at 42CFR 431.52, 431.151, 435.1009, 440.150, 440.220, 442.1, 442.10–442.16, 442 .30, 442.40, 442.42, 442.100–442.119, 483.400–483.480, 488.332, 488.400, and 498.3–498.5; *Form No.:* CMS–3070 (0938–0062); *Use:* The survey forms are needed to ensure provider compliance. In order to participate in the Medicaid program as an ICF/MR, a providers must meet Federal standards. The survey report form is used to record providers' level of compliance with the individual standard and report it to the Federal government. We are considering revising this collection to properly reflect the burden imposed by implementing regulations; *Frequency:* Annually; *Affected Public:* Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 6,763; *Total Annual Responses:* 6,763; *Total Annual Hours:* 21,600.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web site address at *http://cms.hhs.gov/regulations/pra/default.asp,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@hcfa.gov,* or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Attention: Dawn Willinghan, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: March 20, 2003.

Dawn Willinghan,

Acting, Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.

[FR Doc. 03–7306 Filed 3–26–03; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D–0063]

Medical Devices: Guidance for Industry and FDA: Fiscal Year 2003 Medical Device User Fee and Modernization Act of 2002 Small Business Qualification Worksheet and Certification; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''FY 2003 MDUFMA Small Business Qualification Worksheet and Certification.'' This guidance explains how you can certify that you qualify as a ''small business'' within the meaning of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) and provides a copy of, and instructions for, Form FDA 3602, ''FY 2003 MDUFMA Small Business Qualification Certification.'' If FDA decides that you are a small business, you will be eligible for reduced or waived small business fees for medical device applications that you submit from October 1, 2002, through September 30, 2003.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''FY 2003 MDUFMA Small Business Qualification Worksheet and Certification'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and

Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Thomas E. Cardamone, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–0806, ext. 117.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is providing guidance on how you may qualify as a ''small business'' within the meaning of MDUFMA. MDUFMA requires FDA to collect a user fee from each person who submits certain medical device applications for FDA review. MDUFMA user fees range from $2,187 to $154,000, depending on the type of application. The fees for fiscal year (FY) 2003 are summarized in table 1 of this document. A ''small business'' is eligible for reduced or waived fees.

To qualify as a small business, your ''gross receipts or sales,'' including that of all of your affiliates, partners, and parent firms, cannot exceed $30 million. See section 738(d)(2)(A)(i) and (e)(2)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379j(d)(2)(A)(i) and (e)(2)(A)). When you submit an application that is subject to a MDUFMA user fee, you must pay the standard fee unless you have provided information to FDA that demonstrates that you are a small business.

TABLE 1.—FY 2003 MEDICAL DEVICE REVIEW USER FEES[1]

Application	Standard Fee	Small Business
Premarket application (PMA[1], PDP[1], BLA[1])	$154,000	$58,520
Premarket report (premarket application for a reprocessed single-use device)	$154,000	$58,520
First premarket application by a small business	Not applicable	Fee is waived
Panel-track supplement	$154,000	$58,520
Efficacy supplement	$154,000	$58,520
180-day supplement	$33,100	$12,582
Real-time supplement	$11,088	$4,213
510(k)	$2,187	$2,187[2]

[1]PMA means premarket approval applications, PDP means product development protocol, and BLA means biologics license application
[2]During FY 2003, all 510(k) applicants will pay the standard fee. A reduced small business fee will be available beginning FY 2004.

FDA is making this guidance effective immediately because there is a statutory requirement that requires immediate implementation and guidance is needed to help effect such implementation. As soon as Congress enacts an appropriation authorizing FDA to collect and spend MDUFMA user fees, we will begin to collect those fees. You must pay the full standard fee unless you demonstrate you are a small business (section 738(d)(2)(B) and (e)(2)(B) of the act). You will pay a fee for each application you submit on or after October 1, 2002, if that application is subject to a fee. If you do not pay a fee when MDUFMA requires you to do so, FDA will not file or review your application.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on small entities and MDUFMA. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

You may obtain a copy of ''FY 2003 MDUFMA Small Business Qualification Worksheet and Certification'' via your fax machine by calling the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to enter the system. At the second voice prompt press 1 to order a document, then enter the document number (1204) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

You may also obtain a copy of the guidance through the Internet. FDA provides this guidance and additional information on MDUFMA at http://www.fda.gov/oc/mdufma. FDA periodically updates this site to provide you the most current information and guidance concerning the MDUFMA program.

IV. Paperwork Reduction Act

This draft guidance contains a collection of information that requires clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

V. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this guidance. Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Electronic comments may be submitted at http://www.fda.gov/dockets/ecomments. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 12, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 03–7374 Filed 3–25–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Under the Comprehensive Environmental Response Compensation and Liability Act

Pursuant to 28 CFR 507 notice is hereby given that on March 6, 2003, a proposed Consent Decree in *United States* v. *Archer Daniels, et al.* Civil Action No. 03–CV–1593WJR was lodged with the United States District Court for the Central District of California.

In this action, under sections 106 and 107 of CERCLA, 42 U.S.C. 9606 and 9607, the United States sought injunctive relief and recovery of response costs to remedy conditions in connection with the release or threatened release of hazardous substances into the environment at the Waste Disposal, Inc. Superfund Site in Santa Fe Springs, California (hereinafter referred to as the ''Site'').

The defendants in this action are as follows: Archer Daniels Midland Company; Atlantic Oil Company; Atlantic Richfield Company; Chevron USA, Inc.; Conoco, Inc.; Conopco, Inc.; Dilo, Inc.; Exxon Mobil Corporation; Ferro Corporation; FMC Technologies, Inc. (successor in interest to FMC Corporation); Global Santa Fe Corporation; Halliburton Energy Services, Inc.; McDonnell Douglas Corporation; Shell Oil Company; Texaco, Inc.; Union Pacific Railroad Company; and Union Oil Company of California (Hereinafter referred to collectively as ''the Settlors'')

Under this settlement, the Settlors, which arranged for the disposal of hazardous substances at the Site, have agreed to perform the remedy chosen by EPA to clean up the Site, and pay $1,250,000 of the past response costs of the United States, and pay all of the future response costs of the United States to be incurred at the Site.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, and should refer to *United States* v. *Archer Daniels, et al.,* D.J. Ref. 90–11–2–1000. At the Consent Decree includes a covenant not to sue under section 7003 of RCRA, 42 U.S.C. 6973(d), commenters may request an opportunity for a public meeting in the affected area, in accordance with section 7003(d) of RCRA, 42 U.S.C. 6973(d).

The Consent Decree may be examined at U.S. EPA Region IV, 75 Hawthorne Street, San Francisco, CA 94107. During the public comment period, the Consent Decree, may also be examined on the following Department of Justice Web site, *http://www.usdoj.gov/enrd/open.html.* A copy of the Consent Decree may also be obtained by mail from the Consent Decree Library, PO Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax no. (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy from the Consent Decree Library, please enclose a check in the amount of $112.75 (25 cents per page reproduction cost) payable to the U.S. Treasury. In requesting a copy exclusive of exhibits and defendants' signatures, please enclose a check in the amount of $28.50 (25 cents per page reproduction cost) payable to the U.S. Treasury.

W. Benjamin Fisherow,

Deputy Chief, Environmental Enforcement Section.

[FR Doc. 03–7294 Filed 3–26–03; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decrees Pursuant to the Comprehensive Environmental Response, Compensation and Liability Act

In accordance with CERCLA section 122(d)(2), 42 U.S.C. 9622(d)(2), and Departmental policy in 28 CFR 50.7, notice is hereby given that on March 7, 2003, two proposed Consent Decrees in *United States* v. *GPU, Inc.,* et al, consolidated Civil Action Nos. 96–338, and 97–468, were lodged with the United States District Court for the District of Delaware.

In this action, the United States sought: implementation of a unilateral administrative order issued by the U.S. Environmental Protection Agency (''EPA''), civil penalties for failure to comply with that order, and recovery of environmental response costs incurred and to be incurred by the United States, all in connection with the Dover Gas Light Superfund Site, located in Dover, Delaware (''Site''). The first Consent Decree requires General Public Utilities, Inc. (''GPU''), now known as FirstEnergy, to pay $700,000 in response costs, pay a civil penalty of $100,000, perform environmental studies near the Site, and in conjunction with co-plaintiff Chesapeake Utilities Corporation, pay EPA $1,700,000 for any groundwater remedy that may be implemented in the future. A second Consent Decree resolves claims against the State of Delaware. The State of Delaware is required to pay $1,000,000, for reimbursement of response costs incurred by EPA and Chesapeake Utilities, and to perform maintenance work at the Site.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the Consent Decrees. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, PO Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, and should refer to *U.S.* v. *GPU,* et al., D.J. Ref. # 90–11–2–1055. The Consent Decrees may be examined at the Office of the United States Attorney, c/o Patricia Hannigan, Assistant United States Attorney, 1201 Market Street, Wilmington, DE 19801, and at U.S. EPA Region III, c/o Patricia Miller, Senior Regional Counsel, 1650 Arch Street, Philadelphia, PA 19103. During the public comment period, the Consent Decrees may be examined on the DOJ Web site: *http://www.usdoj.gov/enrd/open.html.* A copy of the Consent Decrees may also be obtained by mail from the Consent Decree Library, PO Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax no. (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy from the Consent Decree Library, please enclose a check in the amount of $11.00 for the *U.S.* v. *Delaware* Consent Decree, and $40.00 for the *U.S.* v. *GPU* Consent Decree (25 cents per page reproduction cost) payable to the U.S. Treasury. In requesting a copy of the FirstEnergy Consent Decree exclusive of exhibits and Defendants' signatures, please enclose a check in the amount of $22.25 payable to the U.S. Treasury.

Robert Brook,

Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 03–7295 Filed 3–26–03; 8:45 am]

BILLING CODE 4410–15–M