ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Forms	Number of respondents	Responses per respondent	Avg. burden per response (in hrs.)
Follow-up	833	1	25/60

Dated: September 28, 2005.

Betsey Dunaway,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 05–19881 Filed 10–3–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Agency Recordkeeping/Reporting Requirements Under Emergency Review by the Office of Management and Budget (OMB)

Title: Child Care and Development Fund (CCDF) Center-Based Provider List.

OMB No.: New request.

Description: The purpose of this request is to collect a list of center-based providers receiving CCDF funding in FY 2004. The Department will use this information to determine the involvement of Faith-Based and Community Organizations (FBCOs) in the CCDF program, the amount of funds used by different types of center-based providers and the mechanism through which center-based providers receive CCDF funds in each State.

The Faith-Based and Community Initiative (FBCI) is included in the President's Management Agenda, and the U.S. Department of Health and Human Services (HHS) is required to participate in the Initiative under several Executive Orders and regulations.

On January 29, 2001, Executive Order (EO) 13198, Agency Responsibilities with Respect to Faith-Based and Community Initiatives, charged the Department with identifying and eliminating regulatory, contracting and other obstacles that prevent full participation of FBCOs in the Department's programs (66 FR 8497). On December 12, 2002, EO 13279, Equal Protection of the Laws for Faith-Based and Community Organizations, charged the Department with ensuring equal treatment for FBCOs that apply to participate in the Department's programs (67 FR 77141).

On July 16, 2004, HHS published a final rule, ''Participation in Department of Health and Human Services Programs by Religious Organizations; Providing for Equal Treatment of All Department of Health and Human Services Program Participants,'' which ensured equal treatment for faith-based organizations regarding participation in HHS programs.

As part of the Department's effort to fulfill its responsibilities under these Executive Orders and as part of the HHS Child Care Bureau's statutory authority provider under Section 658K(a)(1)(B) of the Child Care and Development Block Grant of 1990, the Department will request data from State lead agencies involved in administering Federal funds through CCDF.

States have considerable latitude in administering and implementing their child care subsidy programs, including contracting with center-based providers within the State for child care slots to serve low-income families eligible for CCDF. The purpose of this request for data from the States is to collect a list of those center-based providers contracted directly by the State, or serving CCDF-subsidized children through receipt of vouchers or certificates, in FY 2004. The Department will use this information to determine the involvement of FBCOs in the CCDF program, the amount of funds used by different types of center-based providers and the mechanism through which center-based providers receive CCDF funds in each State.

Respondents: States, the District of Columbia and the Territories, including Puerto Rico, Guam, the Virgin Islands, American Samoa and the Northern Mariana Islands.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–901	56	1	16	896

Estimated Total Annual Burden Hours: 896 hours.

Additional Information: ACF is requesting that OMB grant a 180-day approval for this information collection under procedures for emergency processing by October 21, 2005. A copy of this information collection, with applicable supporting documentation, may be obtained by calling the Administration for Children and Families, Cheryl Vincent at (202) 205–0750. In addition, a request may be made by sending an e-mail request to: *cvincent@acf.dhhs.gov.*

Comments and questions about the information collection described above should be directed to the following address by October 21, 2005: Office of Information and Regulatory Affairs, Office of Management and Budget, Paperwork Reduction Project, Desk Officer for ACF, E-mail: *Katherine_T._Astrich@omb.eop.gov.*

Dated: September 28, 2005.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 05–19787 Filed 10–3–05; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0364]

Third Annual Stakeholder Meeting on the Medical Device User Fee and Modernization Act of 2002; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public meeting: Third Annual Stakeholder Meeting on the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). On October 1, 2007, the user fee provisions of MDUFMA will expire. In preparation for discussions regarding legislation to reauthorize and possibly modify MDUFMA user fees, the agency is holding this public meeting to obtain stakeholder input and recommendations on various issues related to this future legislation.

DATES: The public meeting will be held on November 17, 2005, from 9 a.m. to 5 p.m. However, depending upon the level of public participation, the meeting may end early. Registration is required by October 28, 2005. All individuals wishing to make a presentation or to speak on an issue should indicate their intent and the topic to be addressed and provide an abstract of the topic to be presented by October 28, 2005.

ADDRESSES: The public meeting will be held at the Gaithersburg Hilton, 620 Perry Pkwy., Gaithersburg, MD.

Submit written requests to make an oral presentation to Cindy Garris (see **FOR FURTHER INFORMATION CONTACT**). Include your name, title, firm name, address, telephone, and fax number with your request. All requests and presentation materials should include the docket number found in brackets in the heading of this document. Submit all requests for suggestions and recommendations to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Cindy Garris, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597, ext. 121, FAX: 301–443–8818, e-mail: *cxg@cdrh.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On October 26, 2002, MDUFMA amended the Federal Food, Drug, and Cosmetic Act (the act) to include several new significant provisions. In addition to authorizing user fees for the review of certain premarket applications, MDUFMA authorizes the following provisions: (1) Establishment of performance goals (cycle and decision) for premarket approval applications (PMAs), biologics license applications, and premarket notifications (510(k)), (2) authorization of good manufacturing practice (GMP) inspections by FDA-accredited persons (third-parties), and (3) establishment of new requirements for reprocessed single-use devices. In a letter that accompanied the user fee legislation, the agency also committed to developing performance goals for modular PMAs, maintaining performance in those programs without MDUFMA performance goals, and improving the timeliness of inspections conducted under the GMP and Bioresearch Monitoring (BIMO) programs.

MDUFMA has been amended twice since its enactment. The Medical Devices Technical Corrections Act (Public Law 108-214) (April 1, 2004), clarified Congress's intent in areas where MDUFMA was unclear, and improved and expanded some features of MDUFMA. The Medical Device User Fee Stabilization Act of 2005 (Public Law 109-43) (August 1, 2005) provides a new fee structure and a new definition of ''small business'' for FY 2006 and FY 2007; it also limits section 301 of MDUFMA (section 502(u) of the act (21 U.S.C. 352(u)) to reprocessed single-use devices.

Since its passage in October 2002, the agency has been working to implement MDUFMA. An important part of this process has been the annual stakeholder meetings. Each year, FDA has held public meetings to afford interested persons the opportunity to share information and views on the implementation of MDUFMA.

On October 1, 2007, the user fee provisions of MDUFMA will expire. In order to help the agency and all stakeholders to evaluate the program and prepare for possible new legislation to reauthorize MDUFMA, FDA would like to hear from interested parties about those aspects of MDUFMA that worked well and those areas for which change should be considered. Specifically, FDA is looking for input and recommendations that may help to improve the device review program. FDA is holding this public meeting to gather such information from its stakeholders.

For additional information on MDUFMA, please see the document entitled ''Background on MDUFMA'' at *http://www.fda.gov/cdrh/mdufma/whitepaper.html*.

II. Agenda

On November 17, 2005, FDA is providing the opportunity for interested persons to share their views on the following topics:

- User Fee Structure—During this session, the agency will seek comments on possible user fee structures for MDUFMA II that will provide for an adequate and stable revenue base and predictable user fees.
- Premarket Review Performance Goals—During this session, interested persons may discuss the current performance goals and make recommendations for additional or alternative goals that would help to provide for timely and predictable reviews.
- Qualitative Performance Goals (e.g., Modular PMA, GMP, and BIMO Inspection Programs)—During this session, stakeholders may comment on the current qualitative performance goals and make recommendations for agency consideration of new initiatives of importance to stakeholders.
- Third-Party Inspection Program—During this session, FDA will seek recommendations for improving the participation of eligible manufacturers in the inspection program.
- Reprocessing of Single-Use Devices (SUDs)—During this session, interested stakeholders may comment on current requirements for reprocessing SUDs and make recommendations for ways the agency can provide for the continuing assurance of safe and effective reprocessed SUDs.
- Other Provisions—At the conclusion of the meeting, there will be an opportunity for a general discussion from the floor.

As stated previously, although the meeting is scheduled for a full day, depending upon the level of public participation, the meeting may end early.

III. Registration

Online registration for the meeting is required by October 28, 2005. Acceptance will be on a first-come, first-served basis. There will be no onsite registration. Please register online at *http://www.fda.gov/cdrh/meetings/120303.html*. FDA is pleased to provide the opportunity for interested persons to listen from a remote location to the live proceedings of the meeting. In order to ensure that a sufficient number of call-in lines are available, please register to listen to the meeting at *http://www.fda.gov/cdrh/meetings/120303.html* by October 28, 2005. Persons without Internet access may register for the onsite meeting or to listen remotely by calling 301–443–6597, ext. 121 by October 28, 2005.

If you need special accommodations due to a disability, please contact Cindy Garris at least 7 days in advance of the meeting.

IV. Request for Input and Materials

FDA is also interested in receiving input from stakeholders on other issues

related to future user fee legislation. Send suggestions or recommendations to the Division of Dockets Management (see **ADDRESSES**).

FDA will place an additional copy of any material it receives on the docket for this document (2005N–0364). Suggestions, recommendations, and materials may be seen at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday (see **ADDRESSES**).

V. Transcripts

Following the meeting, transcripts will be available for review at the Division of Dockets Management (see **ADDRESSES**).

Dated: September 22, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–19864 Filed 9–29–05; 3:11 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0342]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: AFP-L3% Immunological Test Systems; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document: AFP-L3% Immunological Test Systems.'' This guidance document describes a means by which AFP-L3% (alpha-fetoprotein L3 subfraction percent) immunological test systems may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify AFP-L3% immunological test systems into class II (special controls). This guidance document is immediately in effect as the special control for AFP-L3% immunological test systems, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Class II Special Controls Guidance Document: AFP-L3% Immunological Test Systems'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Maria Chan, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0493

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying AFP-L3% immunological test systems into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). This document announces the guidance document that will serve as the special control for AFP-L3% immunological test systems. Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act (21 U.S.C. 360c(a)(1)). FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification. Because of the timeframes established by section 513(f)(2) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Therefore, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidance represents the agency's current thinking on AFP-L3% immunological test systems. 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

To receive ''Class II Special Controls Guidance Document: AFP-L3% Immunological Test Systems'' by fax, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1570) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork