emergency/disaster, or for which there are sufficiently small numbers of manufacturers such that disruption of manufacture or loss of one or more of these manufacturers would create a shortage.

In the **Federal Register** of December 19, 2008 (73 FR 77718), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of the Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
903(d)(2)	125	3	375	0.5	188

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

FDA based the burden estimates in Table 1 on past experience with direct contact with the medical device manufacturers, and anticipated changes in the medical device manufacturing patterns for the specific devices being monitored. FDA estimates that approximately 125 manufacturers would be contacted by telephone and/or electronic mail 3 times per year to either obtain primary data or to verify/validate data. Because the data being requested represent data elements that are monitored or tracked by manufacturers as part of routine inventory management activities, it is anticipated that for most manufacturers, the estimated time required of manufacturers to complete the data request will not exceed 30 minutes per request cycle.

Dated: March 9, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–5545 Filed 3–13–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0051]

Draft Guidance for Industry and Food and Drug Administration; User Fees and Refunds for Premarket Approval Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''User Fees and Refunds for Premarket Approval Applications'' (PMAs). The purpose of this draft guidance document is to outline the types of PMAs subject to user fees, including supplements and other submissions, as well as those that do not have an associated user fee. The draft guidance also identifies industry and FDA actions on these submissions that may result in a refund of the fee.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by April 15, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''User Fees and Refunds for Premarket Approval Applications,'' 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, or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft 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.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Nicole Wolanski, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4010.

Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 5515 Security Lane, rm. 130, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107–250) amends the Federal Food, Drug, and Cosmetic Act (the act) to provide FDA new responsibilities and resources associated with the collection and refund of user fees. The primary difference between this draft guidance and the November 24, 2003, version now in effect is the addition of user fee and user fee refund information for 30-day notices and periodic reports. Additionally, the draft guidance discusses the modified user fee refund provisions for modular PMAs. If finalized, this draft guidance will supersede the 2003 guidance.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on user fees and refunds for premarket approval applications. 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

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive ''User Fees and Refunds for Premarket Approval Applications,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document, or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number (1681) to identify the guidance you are requesting.

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 at *http://www.regulations.gov* or the CBER Internet site at *http://www.fda.gov/cber/guidelines.htm*.

IV. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (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.

Title: User Fees and Refunds for Premarket Approval Applications.

Description: Section 738 of the act requires the payment of user fees for devices subject to premarket approval (PMA) under section 515 of the act (21 U.S.C. 360e). Section 738(j) of the act allows for refunds of these fees in certain circumstances. This draft guidance document describes requirements associated with user fees and FDA's recommendation for the kind of information to include in a request for a refund.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Federal Food, Drug, and Cosmetic Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
738(j)	17	1	17	0.5	9

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

The industry-wide burden estimate is based on an FDA actual average fiscal year (FY) annual rate of receipt of 17 refund requests, using FY 2005 through 2007 data.

This draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 814, subparts B and E have been approved under OMB control number 0910–0231.

V. Comments

Interested persons may submit to the Division of Dockets Management (See **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 4, 2009.

Daniel G. Schultz,

Director, Center for Devices and Radiological Health.

[FR Doc. E9–5543 Filed 3–13–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0052]

Draft Guidance for Industry on Documenting Statistical Analysis Programs and Data Files; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry #197 entitled ''Draft Guidance for Industry on Documenting Statistical Analysis Programs and Data Files.'' The purpose of this draft guidance is to simplify the preparation and evaluation of submissions in support of new animal drug applications by providing a uniform system for documenting statistical analysis programs and data files.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by June 1, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the draft 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.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.