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.

FOR FURTHER INFORMATION CONTACT: Robert Abugov, Center for Veterinary Medicine (HFV–105), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8168, *Robert.abugov@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

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.'' This draft guidance provides recommendations to study statisticians for documenting statistical analyses and data files submitted to the Center for Veterinary Medicine (CVM) for the evaluation of safety and effectiveness in new animal drug applications. These recommendations are intended to reduce the number of revisions that may be required for CVM to effectively review statistical analyses and to simplify submission preparation by providing a uniform documentation system.

II. Significance of Guidance

This level 1 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 this topic. 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 statutes and regulations.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 514 have been approved under OMB control no. 0910–0032.

IV. 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.

V. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/cvm* or *http://www.regulations.gov*.

Dated: March 10, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–5650 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–N–0664]

Industry Exchange Workshop on Food and Drug Administration Drug and Device Requirements; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Chicago District, in cosponsorship with the Association of Food and Drug Officials (AFDO), is announcing a public workshop entitled ''Drugs and Devices—Promoting and Protecting the Public Health Through Risk Management and Product Cycle Improvement.'' This 2-day public workshop is intended to provide information about FDA drug and device regulation to the regulated industry.

Date and Time: The public workshop will be held on Monday, June 8, 2009, from 10:20 a.m. to 5 p.m. and Tuesday, June 9, 2009, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Doubletree Hotel Chicago—Oakbrook, 1909 Spring Rd., Oak Brook, IL 60523, 800–222–TREE, 800–222–8733, or 630–472–6000, FAX: 630–573–1909.

Attendees are responsible for their own accommodations. To make reservations at the Doubletree Hotel Chicago—OakBrook, at the reduced conference rate, contact the Doubletree Hotel Chicago—OakBrook before May 5, 2009, citing meeting code ''AFDO Conference''.

Contact: William Weissinger, Food and Drug Administration, 550 W. Jackson Blvd., 15th Fl., Chicago, IL 60661, 312–596–4210, FAX: 312–596–4242, e-mail: *William.weissinger@fda.hhs.gov*.

Registration: You are encouraged to register by May 12, 2009. The AFDO registration fees cover the cost of facilities, materials, and breaks. Seats are limited; please submit your registration as soon as possible. Course space will be filled in order of receipt of registration. Those accepted into the course will receive confirmation. Registration will close after the course is filled. Registration at the site is not guaranteed but may be possible on a space available basis on the day of the public workshop beginning at 7:30 a.m. The cost of registration follows:

COST OF REGISTRATION

Affiliation	Fee
Government (AFDO/North Central AFDO Member)	$395.00
Government (Non-Member)	$495.00
Non-Government (AFDO/NCAFDO Member)	$450.00
Non-Government (Non-Member)	$550.00
To be added to registration fee for workshop registration postmarked after May 12,2009	$75.00

If you need special accommodations due to a disability, please contact William Weissinger at least 7 days in advance of the workshop.

Registration instructions: To register, please submit your name, affiliation, mailing address, phone, fax number, and e-mail, along with a check or money order payable to ''AFDO.'' Please mail your payment to: AFDO, 2550 Kingston Rd., suite 311, York, PA 17402. To register via the Internet, go to *www.afdo.org*. (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**).

The registrar will also accept payment by major credit cards (VISA/MasterCard only). For more information on the meeting, or for questions on registration, contact AFDO, 717–757–2888, FAX: 717–755–8089, or e-mail: *afdo@afdo.org*.

SUPPLEMENTARY INFORMATION: The public workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The workshop will provide FDA-regulated drug and device entities with information on a number of topics concerning FDA requirements related to the production and marketing of drugs and/or devices. Topics for discussion include the following: