of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR 860.123 have been approved under OMB control number 0910–0138.

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: April 23, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–9937 Filed 4–28–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0144]

Draft Guidance for Industry and Food and Drug Administration Staff; User Fees for 513(g); Requests for Information; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Draft Guidance for Industry and FDA Staff; User Fees for 513(g) Requests for Information." This draft guidance describes the user fees associated with 513(g) requests for information.

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on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by July 28, 2010. Submit written or electronic comments on the collection of information June 28, 2010.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled "Draft Guidance for Industry and FDA Staff; User Fees for 513(g) Requests for Information" to the Division of Small Manufacturers, International, and Consumer Assistance (DSMICA), WO66, rm. 4613, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, or to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, 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 CDRH to 301–847–8149. 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: Heather S. Rosecrans, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., WO66, rm. 1532, Silver Spring, MD 20993, 301–796–6571, or Stephen Ripley, Center for Biologics Evaluation and Research, HFM–17, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

Section 513(g) of the Federal Food Drug and Cosmetic Act (act) (21 U.S.C. 360c(g)) provides a means for obtaining the FDA's views about classification information and the regulatory requirements that may be applicable to a particular device. Title II of the Food and Drug Administration Amendments Act of 2007 (FDAAA), also termed the Medical Device User Fee Amendments of 2007 (Public Law 110–85), extends FDA's authority to collect medical device user fees by establishing a fee for "a request for classification information." Elsewhere in this **Federal Register** we are publishing a document announcing the availability of a guidance document entitled "Draft Guidance for Industry and FDA Staff; FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act." This guidance describes the procedures we recommend when seeking the Agency's views about classification information and regulatory requirements that may be applicable to a particular device.

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 for requests for classification information submitted in accordance with section 513(g) of the act. 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 "Draft Guidance for Industry and Food and Drug Administration Staff; User Fees for 513(g) Requests for Information," 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 301–847–8149 to receive a hard copy. Please use the document number 1709 to identify the guidance you are requesting.

A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. Guidance documents are also available at *http://www.regulations.gov/search/Regs/home.html#home* or on the CBER Internet site at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm*.

IV. Paperwork Reduction Act of 1995

Under 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: Draft Guidance for Industry and FDA Staff: User Fees for 513(g) Requests for Information

Description: Section 513(g) of the act (21 U.S.C. 360c(g)) provides a means for obtaining the FDA's views about classification information and the regulatory requirements that may be applicable to a particular device. Title II of the Food and Drug Administration Amendments Act of 2007 (FDAAA), also termed the Medical Device User Fee Amendments of 2007, Public Law 110–85, extends FDA's authority to collect medical device user fees by establishing a fee for "a request for classification information." Form No. 3601, Medical Device User Fee Cover Sheet, is being revised to include the addition of user fees for 513(g) Request for Information.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Sec. 738(a)(2)(A)(ix) of FDAAA Sec.513(g) of the FD&C Act	Form FDA No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total hours
CDRH	3601	110	1	110	2	220
CBER	3601	4	1	4	2	8
Total Hours						228

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

FDA based these estimates on the number of 513(g) Requests for Information received by CDRH and CBER during calendar year (CY) 2008. Elsewhere in this **Federal Register** we are publishing a document announcing the availability of a draft guidance document entitled "Guidance for Industry and FDA Staff; FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act." This guidance describes the procedures we recommend when seeking the Agency's views about classification information and regulatory requirements that may be applicable to a particular device. The burden estimate is based on the amount of time needed to satisfy the completion of these procedures.

This draft guidance also 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 807 subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814 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: April 23, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–9938 Filed 4–28–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0210]

Front-of-Pack and Shelf Tag Nutrition Symbols; Establishment of Docket; Request for Comments and Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket; request for comments and information.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of a docket to obtain data and other information that will inform the agency's deliberations about ways to enhance the usefulness to consumers of point-of-purchase nutrition information, such as information on the principal display panel of food products ("front-of-pack" labeling) or on shelf tags in retail stores. In particular, FDA is interested in the following: Data and information on the extent to which consumers notice, use, and understand nutrition symbols on front-of-pack labeling of food packages or on shelf tags in retail stores; research assessing and comparing the effectiveness of particular possible approaches to front-