

Management, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-796-3793.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Guidance for Industry on How to Submit a Protocol Without Data in Electronic Format to the Center for Veterinary Medicine—(OMB Control Number 0910-0524)—Extension**

Protocols for nonclinical laboratory studies (safety studies), are required under 21 CFR 58.120 for approval of new animal drugs. Protocols for adequate and well-controlled effectiveness studies are required under 21 CFR 514.117(b). Upon request by the

animal drug sponsors, the Center for Veterinary Medicine (CVM) reviews protocols for safety and effectiveness studies for which CVM and the sponsor consider this to be an essential part of the basis for making the decision to approve or not approve an animal drug application or supplemental animal drug application. The establishment of a process for acceptance of the electronic submission of protocols for studies conducted by sponsors in support of new animal drug applications, is part of CVM's ongoing initiative to provide a method for paperless submissions. Sponsors may submit protocols to CVM in paper format. CVM's guidance on how to submit a study protocol permits sponsors to submit a protocol without data as an e-mail attachment via the Internet. Further, this guidance also

electronically implements provisions of the Government Paperwork Elimination Act (GPEA). The GPEA required Federal agencies, by October 21, 2003, to provide the following: (1) The option of the electronic maintenance, submission, or disclosure of information, if practicable, as a substitution for paper and (2) the use and acceptance of electronic signatures, where applicable. FDA Form 3536 is used to facilitate the use of electronic submission of protocols. This collection of information is for the benefit of animal drug sponsors, giving them the flexibility to submit data for review via the Internet.

The likely respondents are sponsors of new animal drug applications.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section/ Form No. 3536	Number of Respondents	Annual Frequency per Response	Total Annual Responses <sup>2</sup>	Hours per Response	Total Hours
514.117(b) & 58.120	40	1.8	72	20	14.4

<sup>1</sup> There are no capital or operating and maintenance costs associated with this collection of information.

<sup>2</sup> Electronic submissions received between January 1, 2008, and December 31, 2008.

The number of respondents in table 1 of this document is the number of sponsors registered to make electronic submissions (40). The number of total annual responses is based on a review of the actual number of such submissions made between January 1, 2008, and December 31, 2008, (72 x hours per response (.20) = 14.4 total hours).

Dated: April 26, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-10023 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-0153]

**Draft Guidance for Industry and Food and Drug Administration Staff; Food and Drug Administration and Industry Procedures for Section 513(g) Requests for Information Under the Federal Food, Drug, and Cosmetic Act**

**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; FDA and Industry Procedures for Section 513(g) Requests for Information Under the Federal Food, Drug, and Cosmetic Act." This draft guidance is not final nor is it in effect at this time. Elsewhere in this issue of the **Federal Register**, FDA is also publishing a notice of availability for a draft guidance entitled "Draft Guidance for Industry and FDA Staff; User Fees for 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 comments on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on this draft guidance by July 28, 2010. Submit written or electronic comments on the collection of information by June 28, 2010.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written requests for single copies of the draft 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" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food

and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002, 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, 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 CDRH at 301-847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance and the collection of information 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., Bldg. 66, rm., 1532, Silver Spring, MD 20993-0002, 301-796-6571, or Steve Ripley, Center for Biologics Evaluation and Research, (HFM-17),

Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852, 301-827-6210.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Section 513(g) of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 360c(g) provides a means for obtaining the FDA's views about the classification and the regulatory requirements that may be applicable to a particular device. The purpose of this draft guidance is to establish procedures for submitting, reviewing, and responding to requests for information respecting the class in which a device has been classified or the requirements applicable to a device under the act that are submitted in accordance with section 513(g) of the act. FDA does not review data related to substantial equivalence or safety and effectiveness in a 513(g) Request for Information. FDA's responses to 513(g) Requests for Information are not device classification decisions and do not constitute FDA clearance or approval for marketing. Classification decisions and clearance or approval for marketing require submissions under different sections of the act. Additionally, the act, as amended by the FDA Amendments Act of 2007 (FDAAA) (Public Law 110-85), requires FDA to collect user fees for 513(g) Request for Information. Elsewhere in this issue of the **Federal Register**, FDA is also publishing a notice of availability for a draft guidance entitled "Draft Guidance for Industry and FDA Staff; User Fees for 513(g) Requests for Information."

**II. Significance of Guidance**

This draft guidance is being issued consistent with FDA'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 requirement of the applicable statutes 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 FDA Staff; FDA and Industry Procedures for Section 513(g) Requests for Information Under the Federal Food, Drug, and Cosmetic Act," you may either send an email request to [dsmica@fda.hhs.gov](mailto: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 1671 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> or on the CBER Internet site at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>. Guidance documents are also available at <http://www.regulations.gov>.

**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; FDA and Industry Procedures for Section 513(g) Requests for Information Under the Federal Food, Drug, and Cosmetic Act.

*Description:* Section 513(g) of the act provides a means for obtaining the agency's views about the classification and the regulatory requirements that may be applicable to your particular device. Section 513(g) provides that within 60 days of the receipt of a written request of any person for information respecting the class in which a device has been classified or the requirements applicable to a device under this act, the Secretary of Health and Human Services shall provide such person a written statement of the classification (if any) of such device and the requirements of this act applicable to the device.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

FD&C Act 513(g)	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
CDRH	110	1	110	12	1,320
CBER	4	1	4	12	48
Total					1,368

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA based its estimates on the number of 513(g) Requests for Information received by both CDRH and CBER in 2007-2009. Elsewhere in this issue of the **Federal Register**, FDA is publishing a document announcing the

availability of a draft guidance document entitled "Draft Guidance for Industry and FDA Staff; User Fees for 513(g) Requests for Information."

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. 3501-3502). The collections

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.*

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**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](mailto: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