

Draft Guidance for Industry and FDA Staff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

DRAFT GUIDANCE

This guidance document is for comment purposes only.

Document issued on: April 29, 2010

Submit comments on this draft guidance by the date provided in the *Federal Register* notice announcing the availability of the draft guidance. Submit written comments 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>. You should identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions on the content of this guidance for the Center for Devices of Radiological Health, contact Heather S. Rosecrans at 301-796-6571 or by email at heather.rosecrans@fda.hhs.gov. For questions on the content of this guidance for the Center for Biologics Evaluation and Research, contact the Office of Communication, Outreach and Development at 1-800-835-4709 or 301-827-1800.



**U.S. Department of Health and Human Services
Food and Drug Administration**

**Center for Devices and Radiological Health
Center for Biologics Evaluation and Research**

Preface

Additional Copies

Additional copies are available from the Internet at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm209841.htm>. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance 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. Copies of the guidance are also available from:

Office of Communication, Outreach and Development, HFM-40
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448
Phone: 800-835-4709 or 301-827-1800

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This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

Purpose

The purpose of this 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 Federal Food, Drug, and Cosmetic Act (the Act) that are submitted in accordance with section 513(g) of the Act, 21 U.S.C. 360c(g).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Statutory Requirements for Device Classification

Section 513(a) of the Act (21 U.S.C. 360c(a)) establishes three classes of devices based on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness: class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513(f) of the Act (21 U.S.C. 360c(f)), post-amendments devices (devices that were not in commercial distribution before May 28, 1976, the date the Medical Device Amendments

Contains Nonbinding Recommendations
Draft - Not for Implementation

were enacted) are classified in Class III. However, FDA may reclassify a post-amendments device (as Class I or II) or determine that such a device is "substantially equivalent" (SE)¹ to either another post-amendments device that has been classified into Class I or II or to a pre-amendments device for which premarket approval is not required.² Thus, a post-amendments device may be subject to regulation as a Class I or II device in certain circumstances, including when:

- the device is within a type of device that has been classified into class I or II and FDA has found the device to be SE to a device within such type;
- the device is within a type of pre-amendments device which is to be classified under section 513(b) of the Act (21 U.S.C. 360c(b)) and FDA has found the device to be SE to a device within such type (an unclassified device type); or
- FDA has classified or reclassified the device type in class I or II in accordance with sections 513(f)(2) or 513(f)(3) of the Act (21 U.S.C. 360c(f)(2), (3)).

Pursuant to section 513(d) of the Act (21 U.S.C. 360c(d)), FDA promulgates classification regulations classifying devices by generic type. A "generic type of device" is "a grouping of devices that do not differ significantly in purpose, design, materials, energy source, function, or any other feature related to safety and effectiveness, and for which similar regulatory controls are sufficient to provide reasonable assurance of safety and effectiveness." 21 CFR 860.3(i). FDA has issued regulations classifying the vast majority of pre-amendments devices (devices that were in commercial distribution before May 28, 1976) by generic type of device. See 21 CFR 860.84. Each classification regulation, located at 21 CFR parts 862-892, indicates in which class (I, II, or III) FDA has classified the device type. While the great majority of device classifications codified in 21 CFR parts 862-892 are of pre-amendments devices, some of these classifications are of post-amendments devices.

III. Obtaining Information About a Device

A. General Information

¹ Substantial equivalence is defined at section 513(i) of the Act (21 U.S.C. 360c(i)). FDA generally evaluates substantial equivalence on the basis of a premarket notification submitted pursuant to section 510(k) of the Act (21 U.S.C. 360(k)). Certain devices are subject to a statutory exemption from the 510(k) premarket notification requirement (see sections 510(l) and (m) of the Act).

² A pre-amendments device for which premarket approval is not required could be a pre-amendments device that has been classified into Class I or Class II, a pre-amendments device that has been classified into Class III but for which a regulation under section 515(b) of the Act (21 U.S.C. 360e(b)) requiring the submission of an application for premarket approval (PMA) has not yet been issued, or a pre-amendments device that has not yet been classified.

Contains Nonbinding Recommendations
Draft - Not for Implementation

You can obtain information about device classification and regulatory requirements applicable to a type of device in several ways. FDA's device regulations may be found at 21 CFR parts 800 - 898; the regulations classifying device types are located at 21 CFR parts 862 - 892. The CDRH classification resources (<http://www.fda.gov/cdrh/devadvice/313.html#determine>) on the CDRH web site can help you quickly ascertain how your device type may be classified. You can also obtain information about the regulatory requirements that may apply to a particular type of device on FDA's web site (see resources below).

- Product Classification Database
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm>
- 510(k) Database
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>
- Premarket Application Database
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm>
- Class I and Class II Devices Exempt from 510(k) Requirements
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm>
- Device Guidance Documents
<http://www.fda.gov/cdrh/guidance.html>
- Division of Small Manufacturers International and Consumer Assistance at (800) 638-2041 or (301) 796-7100, or by email at dsmica@cdrh.fda.gov
- Office of Combination Products
<http://www.fda.gov/oc/combination>, 301-427-1934, or by email at combination@fda.gov
- Information regarding particular types of devices regulated by CBER can be found at <http://www.fda.gov/cber/devices.htm>.

If the resources listed above do not address your question, you may contact the premarket review branch chiefs for more information. Contact information for the Office of Device Evaluation (ODE) is available at <http://inside.fda.gov:9003/downloads/CDRH/UCM182912.pdf>. Contact information for the Office of In Vitro Diagnostics Evaluation and Safety (OIVD) is available at <http://www.fda.gov/cdrh/organiz.html#oivddes>. Contact information for CBER is available at <http://www.fda.gov/cber/manufacturer.htm>.

B. Section 513(g) Request for Information

Contains Nonbinding Recommendations
Draft - Not for Implementation

Section 513(g) of the Act (21 U.S.C. 360c(g)) provides a means for obtaining the agency's views about the classification and the regulatory requirements that may be applicable to your particular device. This provision states:

Within sixty 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 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.

Section 513(g) governs requests "for information respecting the class in which a device has been classified or the requirements applicable to a device under [the] Act." Submissions that do not request such information are outside the scope of section 513(g).

If, based solely on the information provided with a 513(g) Request for Information, the product at issue does not appear to be a "device" within the meaning of section 201(h) of the Act (21 U.S.C. 321(h)), FDA will so inform the requester in our response. If, based solely on the information provided with the request, the product does appear to be a "device" within section 201(h) of the Act, FDA will generally provide the following information regarding device classification and applicable FDA regulatory requirements:

- the agency's assessment, based on the information submitted in the request, as to the generic type of device (e.g., classification regulation) that the requester's device appears to be within (if any);
- the class of devices within that generic type (and if there is more than one class within that generic type, the particular class within which the requestor's device appears to fall);
- whether a PMA, 510(k), or neither is required in order to market devices of the particular class within that generic type;
- other requirements applicable to devices of the particular class within that generic type;
- whether a guidance document has been issued regarding the exercise of enforcement discretion over the particular class of devices within that generic type;
- whether additional requirements may apply, such as those applicable to radiation-emitting products.

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. The most common method of seeking a classification decision is to submit a premarket notification in accordance with section 510(k) of the Act (see 21 CFR part 807, subpart E - Premarket Notification Procedures).

Contains Nonbinding Recommendations
Draft - Not for Implementation

FDA's response to a 513(g) Request for Information will not address the specific types of nonclinical, animal, or clinical testing appropriate to support clearance or approval of a marketing application (when required). You may send a pre-submission to the appropriate review branch to receive more specific information about your specific testing recommendations (for CDRH, see <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM073611.pdf>; for CBER, use contact information supplied on the 513(g) Request for Information response letter).

A 513(g) response does not constitute final agency action, but provides responsive information based on the information provided by the requestor.

C. Formal Jurisdictional Determinations within FDA

If it is unclear to you which Center has jurisdiction over your product, [including any combination product for which the lead Center has not yet been determined](#), it may be appropriate to contact the Office of Combination Products (OCP) to discuss your product's jurisdiction and whether to submit a formal Request for Designation (RFD) under section 563 of the Act (21 U.S.C. 360bbb-2) rather than submitting a 513(g) Request for Information. The RFD process is used to obtain a formal agency determination concerning the classification of a product as a drug, device, biological product, or combination product subject to section 503(g) of the Act (21 U.S.C. 353(g)),³ and/or respecting which agency component(s) will regulate the product.

Contact information for OCP and comprehensive information on how to write an RFD can be found at <http://www.fda.gov/oc/combo>.

IV. Submitting a 513(g) Request for Information

A 513(g) Request for Information must be submitted in writing and should be identified as a 513(g) Request for Information.

For submissions to CDRH, two copies of the request should be sent to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

³ Combination product is defined at 21 CFR 3.2(e).

Contains Nonbinding Recommendations
Draft - Not for Implementation

For submissions to CBER, two copies of the request should be sent to:

CBER 513(g) Coordinator
Quality Assurance Staff (HFM 4)
c/o Document Control Center (HDM-99)
Center for Biologics Evaluation and Research
1401 Rockville Pike, Suite 200N
Rockville, MD 20852

User Fees

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) Requests for Information. See section 738(a)(2)(A)(ix) of the Act (21 U.S.C. 379j(a)(2)(A)(ix)). FDA may not accept your 513(g) for review until you have paid all fees owed, including all required establishment registration fees. See section 738(f)(1) of the Act (21 U.S.C. 379j(f)(1)). When FDA has received all fees owed, our review of your 513(g) Request for Information will begin as of that date.

As explained above, if the submission does not request information respecting the class in which a device has been classified and/or the requirements applicable to a device under the Act, it is not a Request for Information governed by section 513(g) of the Act. Such requests do not require a response from FDA. FDA intends to refund any user fee submitted with a request that is not governed by section 513(g) of the Act.

For additional information on user fees for 513(g) Requests for Information see the guidance document “User Fees for 513(g) Requests for Classification Information.”

V. Contents of a 513(g) Request for Information

The 513(g) Request for Information should contain the following:

- a cover letter,
- a description of the device,⁴

⁴ A 513(g) Request for Information should seek classification information and/or regulatory requirements for a single product and may include multiple uses of the product. Requests for classification information and regulatory requirements for multiple products should be divided up so that a separate Request for Information and user fee are submitted for each product.

Contains Nonbinding Recommendations
Draft - Not for Implementation

- a description of what the device is to be used for, and
- any proposed labeling or promotional material for the device and, as applicable, any labeling or promotional material of a similar, legally marketed device, if available.

Cover Letter

Your cover letter should identify your request as a “**513(g) Request for Information.**” Your cover letter should include:

- the date of the request,
- the name of the device,
- your specific question(s) concerning the class in which a device has been classified and/or the regulatory requirements applicable to a device,
- the requestor’s name, address, telephone number, fax number, and email address,⁵ and
- the 513(g) requestor’s signature.

Description of the Device

As applicable, the description of the device should include:

- a list of materials and components used in/with the device,
- photographs, engineering drawings, and/or samples of the device,⁶
- a summary of the device’s operational principles,
- a description of the type and amount of energy to be used or delivered by the device, and
- a description of similar devices in commercial distribution in the United States, if available.

Device Uses

You should include the following information:

- the disease or condition with respect to which the device is to be used,
- prescription versus over-the-counter use,
- part of the body or type of tissue applied to or interacted with,
- frequency of use,
- physiological purpose (e.g., removes water from blood, transports blood, etc.),

⁵You should provide the contact information for a single point of contact. The contact information should be associated with the person submitting the Request for Information as the term person is defined in section 201(e) of the Act.

⁶ Any sample device can be returned at the request of the submitter.

Contains Nonbinding Recommendations
Draft - Not for Implementation

- patient population, and
- any other labeling information related to the patient use of the device.

Labeling

You should provide any proposed labeling, including proposed promotional material for the device or any labeling or promotional material of a similar, legally marketed device. If no proposed labeling is available for the described device or for a similar legally marketed device, this should be noted in the cover letter.

Additions to a 513(g) Request for Information

Once FDA has received your 513(g) Request for Information and user fee, you may not modify that 513(g) request by subsequently adding a new question, use, or technology. We would consider the addition of a new question, use, or technology to a pending Request for Information to be a new 513(g) request subject to an additional user fee, to which we intend to respond separately.

VI. Reviewing a 513(g) Request for Information in CDRH

Upon receipt of the 513(g) Request for Information and the necessary user fee, the Document Mail Center (DMC) will assign an accession number to the 513(g) Request for Information and forward the request to the Program Operations Staff (POS). POS will review the 513(g) Request for Information for completeness and confirm the request is for information respecting the class in which a device has been classified and/or the requirements applicable to a device under the Act. POS will send an "acknowledgement of receipt" letter to the submitter of the 513(g) Request for Information. The 513(g) Request for Information will generally be assigned to a review branch in ODE or OIVD for consideration. Staff from ODE or OIVD and other Offices within CDRH with appropriate scientific and regulatory expertise will review the information provided, meet as necessary, and draft a response for signature by the Deputy Director, ODE or OIVD. The response should be responsive to the regulatory question(s) asked in the 513(g) Request for Information.

VII. Reviewing a 513(g) Request for Information in CBER

Upon receipt of the 513(g) Request for Information, the Document Control Center (DCC) will forward the submission to the CBER 513(g) Coordinator who will assign an accession number to the 513(g) Request for Information. The CBER 513(g) Coordinator will then review the 513(g) Request for Information for completeness, confirm the request is for information respecting the class in which a device has been classified and/or the requirements applicable to a device under

Contains Nonbinding Recommendations
Draft - Not for Implementation

the Act, and send an "acknowledgement of receipt" letter to the submitter of the 513(g) Request for Information. The 513(g) Request for Information will generally be assigned to one of the product review offices for consideration. Staff from the assigned product review office and other personnel within CBER with appropriate scientific and regulatory expertise will review the information provided, meet as necessary, and draft a response for signature by the director of the assigned product review office. The response should be responsive to the regulatory question(s) asked in the 513(g) Request for Information.

VIII. Responding to a 513(g) Request for Information in CDRH or CBER

Our response to a 513(g) Request for Information will be responsive to the questions posed in the request. We intend to issue our response within 60 days of receipt. Our response will generally fall into one of the following categories indicating that, based solely on the information provided in the 513(g) Request for Information, it appears that the product you have identified is:

- a device within the meaning of section 201(h) of the Act, and
 - appears to be an unclassified pre-amendments device type and therefore is subject to the 510(k) requirement;
 - appears to be a post-amendments device type that has not yet been re-classified and therefore is subject to the PMA requirement; or
 - appears to be a device that is a classified device type. We will generally identify the generic type of device (e.g., classification regulation) that your device appears to be within, the class of devices within which your device appears to fall, and the type of submission, if any, required in order to market devices of the particular class within that generic type:
 - Class I or II subject to the 510(k) requirement;
 - Class I or II exempt from the 510(k) requirement;
 - Class III subject to the 510(k) or PMA requirements; OR
- not a device,
 - but may be another type of product regulated by FDA. In this case, we would provide you with contact information for another component within FDA; or
 - and appears not to be a product over which FDA has jurisdiction; OR
- a combination product where it is not clear which Center has primary jurisdiction. If you would like to discuss further the assignment of this product, we recommend you contact the Office of Combination Products.

Contains Nonbinding Recommendations
Draft - Not for Implementation

If your 513(g) Request for Information is incomplete and we are unable to provide information regarding classification and/or applicable requirements because you have not submitted sufficient information to us, we intend to contact the submitter and request additional information. If FDA does not receive a response within 30 days of our request, we intend to issue our response at that time.