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FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act

Guidance for Industry and Food and Drug Administration Staff

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For questions for the Center for Devices and Radiological Health regarding this document, contact ORP: Office of Regulatory Programs/Division of Regulatory Programs 1: Submission Support at 301-796-5640 or OPEQSubmissionSupport@fda.hhs.gov. For questions for the Center for Biologics Evaluation and Research regarding this document contact the Office of Communication, Outreach and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.

U.S. Department of Health and Human Services
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Centers for Biologics Evaluation and Research

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See additional PRA statement in Section VII of the guidance.

Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to http://www.regulations.gov. Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number FDA-2010-D-0153. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

CDRH

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please include the document number GUI00001671 and complete title of the guidance in the request.

CBER

Additional copies are available from the Center for Biologics Evaluation and Research (CBER) by written request, Office of Communication, Outreach, and Development (OCOD), 10903 New Hampshire Ave., WO71, Room 3128, Silver Spring, MD 20903, or by calling 1-800-835-4709 or 240-402-8010, by email, ocod@fda.hhs.gov, or from the Internet at https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.

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FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The purpose of this guidance is to establish procedures for submitting, reviewing and responding to requests for information regarding 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 FD&C Act) that are submitted in accordance with section 513(g) of the FD&C Act.

In general, FDA's guidance documents 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 FD&C Act 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 in addition to general controls), and class III

(premarket approval in addition to general controls).

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

Pursuant to section 513(d) of the FD&C Act, 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." (See 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.

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

III. Obtaining Information About a Device

A. General Information

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 on CDRH's Classify Your Medical Device website 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
- 510(k) Database
- Premarket Approval Database
- De Novo Database
- Class I and Class II Devices Exempt from 510(k) Requirements
- Device Guidance Documents
- Division of Industry and Consumer Education (DICE), 800-638-2041 or 301-796-7100, or by email at DICE@cdrh.fda.gov
- Office of Combination Products, 301-796-8930, or by email at combination@fda.gov
- Information regarding particular types of devices regulated by CBER: https://www.fda.gov/vaccines-blood-biologics/blood-blood-products/approved-blood-products

If the resources listed above do not address your question, you may contact the associated Division management for more information. Contact information for the CDRH Office of Product Evaluation and Quality (OPEQ) is available at the CDRH Management Directory By Organization. Contact information for CBER is available at Contacts in the Center for Biologics Evaluation.

B. Section 513(g) Request for Information

Section 513(g) of the FD&C 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. 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 FD&C Act, 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 FD&C 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 FDA 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 FD&C Act. The most common method of seeking a classification decision is to submit a premarket notification in accordance with section 510(k) of the FD&C Act (see 21 CFR part 807, subpart E - Premarket Notification Procedures).

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 Q-submission to the appropriate Center for review by the appropriate Review Division to receive more specific information about your specific testing recommendations (for CDRH, see IDE Approval Process; 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 FD&C Act rather than submitting a 513(g) Request for Information.[3] 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[4] subject to section 503(g) of the FD&C Act, and/or respecting which agency component(s) will regulate the product.[5]

IV. Submitting a 513(g) Request for Information

A 513(g) Request for Information submission should be identified as a 513(g) Request for Information. While section 745A(b) of the FD&C Act does not require 513(g)s to meet eCopy requirements nor require 513(g)s to be submitted solely in electronic format, FDA recommends that 513(g) submissions be submitted as an eCopy or prepared using the voluntary electronic Submission Template and Resource (eSTAR) for 513(g)s available on FDA's website.[6] Alternatively, one complete paper copy may be submitted. For more information on eCopy and the submission process, refer to the eCopy website and FDA guidance entitled "eCopy Program for Medical Device Submissions." We recommend that the submission include the CDRH Premarket Review Submission Cover Sheet[7] for eCopy submissions made to CDRH or CBER to facilitate correct login and timely routing to the appropriate review group.

If submitting to CDRH, we recommend submission packages be submitted electronically via the CDRH Portal, previously known as the CDRH Customer Collaboration Portal. Once submitted via the CDRH Portal, the 513(g) submission will be received by the CDRH Document Control Center (DCC). Alternatively, submission packages may be mailed to the CDRH DCC. The current mailing address for CDRH's DCC is provided on the eCopy Program for Medical Device Submissions webpage.

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[3] Additional information on how combination products are assigned a lead Center for their premarket review and their regulation is available on OCP's webpage.

[4] Combination product is defined at 21 CFR 3.2(e).

[5] For additional information on RFDs, refer to FDA guidances entitled "How to Write a Request for Designation (RFD)" and "How to Prepare a Pre-Request for Designation (Pre-RFD)"

[6] eSTAR is the only type of electronic submission template, and FDA's preferred submission method, that is currently available to facilitate the preparation of 513(g)s as eSubmissions. For simplicity, the electronic submission created with this electronic submission template is often referred to as an eSTAR. FDA's eSTAR program website provides current information regarding the eSTAR program for CDRH and CBER. See also FDA's guidance "Providing Regulatory Submissions for Medical Devices in Electronic Format – Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act."

[7] See Form 3514

For products regulated by CBER, we recommend that submission packages be submitted electronically through the FDA Electronic Submission Gateway. Alternatively, they can be submitted through the CBER submission email inbox (150MB max) at CBERDCC_eMailSub@fda.hhs.gov, or via mail to the CBER DCC. Additional information on the FDA Electronic Submission Gateway and the current mailing address for the CBER DCC can be found at CBER's Regulatory Submissions website.

User Fees

Section 738(a)(2)(A)(ix) of the FD&C Act requires FDA to collect user fees for 513(g) Requests for Information. 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 FD&C Act. When FDA has received all fees owed and the 513(g) submission, 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 FD&C Act, it is not a Request for Information governed by section 513(g) of the FD&C 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 FD&C Act.

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

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

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

- a signed cover letter,
- a description of the device,[8]
- 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,

[8] 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.

- 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,[9] [10] 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, [11]
- a summary of the device's operational principles (e.g., contains software/firmware),
- 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.),
- patient population;
- environment of use; and

[9] You 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 FD&C Act.
[10] For additional information about email communications with CBER, please see SOPP 8119: Use of Email for Regulatory Communications.
[11] Any sample device can be returned at the request of the submitter.

- 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. 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 FD&C 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 reclassified 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 device 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 for 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.

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 may consider a 513(g) to be withdrawn. In this instance, FDA may issue a notice of withdrawal.

VII. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521).

The time required to complete this information collection is estimated to average 12 hours per response, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection.

Send comments regarding this burden estimate or suggestions for reducing this burden to:

FDA PRA Staff,
Office of Operations, Food and Drug Administration
PRAStaff@fda.hhs.gov

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0705 (To find the current expiration date, search for this OMB control number available at https://www.reginfo.gov).