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Client Alert

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FDA Publishes Guidance for Industry on How to Write a Request for Designation

The Food and Drug Administration (FDA) announced on Monday, April 18, 2011, the availability of a guidance document for the industry entitled "How to Write a Request for Designation (RFD)." The guidance, which supersedes the previous RFD guidance document issued in 2005, is intended to do the following:

1. Clarify the type of information the Office of Combination Products (OCP) recommends that a sponsor include in an RFD;
2. Help the sponsor understand what information the agency requires to determine the regulatory identity or classification of a product as a drug, device, biological product or combination product; and
3. Assign the product to the appropriate agency component for review and regulation.

A combination product comprises one of the following combinations:

- A drug and a device;
- A biological product and a device;
- A drug and a biological product; or
- A drug, a device and a biological product.[1]

An RFD is also referred to as an applicant's letter of request.[2] RFDs generally request a determination of (1) the regulatory identity or classification of a product as a drug, device, biological product, or combination product, and (2) either the component of the FDA that will regulate the product if it is a non-combination product, or which Agency Center will have primary jurisdiction for premarket review and regulation if it is a combination product. A letter of designation[3] is the FDA's formal response to an RFD and is a binding determination with respect to classification and/or center assignment that may be changed only under certain conditions.[4] For example, if there is a change in an intended use or component of the product, a new determination may be appropriate.

The RFD should be submitted to the FDA before filing any investigational or marketing application for the product to avoid a potential stay of the review clock if the classification or assignment of the product is unclear or is disputed. In most cases, the FDA will be able to make its determination based on

1 21 C.F.R. 3.2(e) Examples of combination products are available at http://www.fda.gov/CombinationProducts/AboutCombinationProducts/ucm101598.htm.
2 See 21 C.F.R. § 3.2(j)
3 See 21 C.F.R. § 3.2(i)
4 See 21 U.S. § 360bbb-2 and 21 C.F.R. § 3.9

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a well-written RFD. This guidance provides specific recommendations for the format and content of the RFD submission, including the following components:

- The description of the product;
- The intended use / indications of the product;
- The mode(s) of action of the product;
- The primary mode of action (PMOA) of the product;
- The basis for the applicant's PMOA determination;
- The assignment algorithm; and
- The applicant's classification and assignment recommendations.

In an appendix to the guidance, the FDA provides an RFD "Screening Checklist," which serves as a useful resource to ensure your RFD submission includes all required information.

Of course, consistent with the FDA's good guidance practices regulation,[5] the FDA's guidance does not create or confer any rights to the applicant and does not operate to bind the FDA. Applicants are free to use an alternative approach so long as the approach satisfies the requirements of the applicable statutes and regulations. However, because this guidance does represent the FDA's current thinking on the use and content of the RFD, it should be studied carefully by companies developing combination products.

A copy of the guidance document is available here.[6]

5 21 C.F.R. § 10.115
6 http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM251544.pdf