FDA Provides Guidance on How to Formally Request Informal Feedback on Product Designation from the Office of Combination Products

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Earlier this month, the Office of Combination Products of the Food and Drug Administration issued a final guidance for industry, *How to Prepare a Pre-Request for Designation (Pre-RFD)*.[1] The final guidance does not vary significantly from the draft, and it provides not only useful information for industry on how to submit a request and what to include, but also sets forth FDA's intent to respond within 60 days and describes the internal review process.

Background

OCP has long had a formal Request for Designation procedure that is binding on both the agency and industry.[2] The practice of requesting informal (i.e., nonbinding) feedback from OCP has been commonly employed by product developers, as well. In order to bring more consistency, transparency and predictability to the informal feedback process, FDA (OCP) has issued this guidance which makes the formerly informal more formal, but still nonbinding.

The Pre-RFD process can be used to obtain FDA's preliminary, nonbinding assessment of:

- the regulatory identity or classification of a product as a drug, device, biological product, or combination product, and/or
- whether CBER, CDER, or CDRH will regulate the product if it is not a combination product, or which of the centers will have primary jurisdiction if it is a combination product.

On the process side, OCP intends to review the Pre-RFD submission to ensure it has adequate information to make a preliminary assessment within 5 business days. OCP will contact the submitter within that time either saying the assessment will proceed or detailing the additional information required before OCP can proceed. This initial "file review" will eliminate situations in which a company seeking feedback finds out OCP will not be able to provide feedback after waiting several weeks. OCP also intends to provide feedback within 60 calendar days of receiving "complete information" to begin the review. The Guidance states that OCP's review will include involvement of the relevant centers, and, as necessary, the Office of Chief Counsel. It is also notable that the Guidance encourages submitters (more than once) to contact OCP before submitting the Pre-RFD.

The Guidance describes the type of basic information that a Pre-RFD should contain and includes a checklist. The submission should follow the checklist and use the same headings. The items included are what one would expect (e.g., description of product, proposed use/indication, explanation of how the product works, known methods of action and the mechanism by which each is achieved). More notably, FDA stresses (again, more than once) that a succinct summary of the information relevant for OCP to make its assessment is encouraged and that "submission of extraneous information can be counterproductive."

1 Available at https://www.fda.gov/RegulatoryInformation/Guidances/ucm534661.htm.
2 21 CFR part 3.

AGG Observations

- As is the case with most other submissions to the agency, companies will do well to heed FDA's advice to keep the submission succinct and on point. This isn't the place to talk about how promising preliminary results are or how the product will fill an unmet need.

- Although it's not binding, the preliminary assessment shouldn't be ignored and the agency promises the response will include a "thorough and detailed rationale." This level of detail will serve as the roadmap for those who disagree with a preliminary assessment to take a run at requesting another Pre-RFD or a formal RFD in an attempt to change the preliminary assessment.

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