
Manual of Standard Operating Procedures and Policies

General Information

Request For Designation

SOPP 8003

Version #1

Date: September 22, 1997

1. Purpose

Establish CBER policy and procedures for responding to a request for designation (RFD) of product jurisdiction.

2. Background

21 CFR part 3 specifies how FDA will determine the organizational component within FDA designated to have primary jurisdiction for the premarket review and regulation of products that are comprised of any combination of a drug, device, and/or biological. 21 CFR part 3 also sets forth procedures for determining which Agency component will have primary jurisdiction for a drug, device or biological product where jurisdiction is unclear or in dispute.

CBER, CDRH, and CDER have entered into agreements clarifying product jurisdictional issues. These intercenter agreements are nonbinding determinations designed to provide useful guidance to the public. For a combination product not covered by a guidance document or for a product where the agency component with primary jurisdiction is unclear or in dispute, the sponsor of an application should follow the procedures set forth in 21 CFR 3.7 to request a designation of the agency component with primary jurisdiction before submitting the application.

The FDA Ombudsman (HF-7), as product jurisdiction officer, is authorized to determine whether CBER, CDRH, or CDER has primary responsibility for premarket review and regulation of a product that is comprised of a combination of a drug, device, or biological product under the FD&C Act or that is a drug, device, or biological product where the center with primary jurisdiction is unclear or is in dispute.

3. References

Title 21, Code of Federal Regulations, Part 3 - Product Jurisdiction

Title 21, Code of Federal Regulations, Part 10 - Administrative Practices and Procedures

4. Definitions

Key Contact

The individual in each product office designated to coordinate the Office's response to a RFD.

Subject Expert

An individual within a product office identified as having the necessary expertise and experience to evaluate a RFD.

5. Policy

It is the policy of CBER that:

- a response to a formal RFD, forwarded by the Agency Product Jurisdiction Officer, will be issued within 21 days of receipt in the center of the RFD;
- input from each product office will be considered in the development of the response to the RFD;
- a response to formal RFDs will be coordinated by the Center's Ombudsman (HFM-4), and
- a file will be maintained containing the response to formal RFDs.

6. Procedures

Agency Level Procedures

- A formal Request for Designation (RFD) from a sponsor is received by the FDA's Ombudsman's Office, as codified in 21 CFR 3.7.
- Each RFD is reviewed for completeness within 5 working days of receipt by the FDA Ombudsman's office. The sponsor of an accepted request for designation will be notified of the filing date.
- The FDA Ombudsman's office forwards a copy of each RFD to the designated contact for product jurisdiction in CBER, CDRH, and CDER.
- Within 60 days of the filing date of a RFD, the product jurisdiction office will issue a letter of designation to the sponsor with copies to the centers. The letter identifies, and is copied to, the agency component having primary jurisdiction for the premarket review and regulation of the product at issue.

Center Level Procedures

- General Procedures for RFDs are:
 - Within 3 days of its receipt, the CBER Ombudsman will distribute copies of the RFD to the designated key contacts representing the three product offices in the Center:
 - Office of Blood Research and Review
 - Office of Therapeutics Research and Review
 - Office of Vaccines Research and Review
 - The key contact person may delegate the review of the RFD to appropriate office subject experts, and will compile all office comments.
 - A final recommendation will be issued from each Office's key contact, with concurrence by the Office Director, to the CBER Ombudsman. The recommendation will include the identification of agency component which should have primary jurisdiction with an accompanying statement of reasons.
 - The recommendation will be provided to the CBER Ombudsman at least 3 days prior to the 21-day Center Review due date designated on the original RFD cover sheet from the FDA Ombudsman.
 - The CBER Ombudsman will contact the key contacts and Office Directors for further discussion and final resolution if the recommendations reach different conclusions or are inconsistent with previous Center decisions.
 - The CBER Ombudsman will forward CBER's recommendation to the FDA Ombudsman.
 - The CBER Ombudsman will inform all CBER offices of the designation decision.
 - If the designation decision is appealed, the CBER Ombudsman will work with the FDA Ombudsman and appropriate CBER staff to seek resolution.
- Procedures for Informal Requests for Designation are:
 - In some cases, questions concerning designation of product jurisdiction may be informal and not

filed with the FDA Ombudsman.

- Staff within the product offices may respond to informal requests. Unless the request deals only with straightforward issues that would not normally require decision at the Agency level, the individual responding should:
 - inform the inquirer that the response does not represent a formal CBER position,
 - document the information provided to the sponsor, and
 - inform the associated key contact person and CBER Ombudsman of the guidance given.
- The CBER Ombudsman is the contact and coordinator for resolution of questions regarding jurisdiction of products within CBER.
- Documentation procedures are:
 - The CBER Ombudsman will maintain a file of all designation requests, recommendations, and decisions.
 - The file will help ensure consistency by documenting the decision making process and providing precedent through historical reference.

7. Contact

The CBER Ombudsman is the designated CBER contact for Requests for Designations.

The Ombudsman is located in the Office of the Center Director.

8. Effective Date

September 22, 1997

9. History

Written/Revised	Approved	Approval Date	Version Number	Comment
P. Hodges	R. Devine	9/22/1997	1	Original Document.

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