

Food and Drug Administration, HHS

§ 3.5

(p) *Sponsor* means “applicant” (see § 3.2(c)).

[56 FR 58756, Nov. 21, 1991 as amended at 64 FR 398, Jan. 5, 1999; 64 FR 56447, Oct. 20, 1999; 68 FR 37077, June 23, 2003; 70 FR 49861, Aug. 25, 2005]

§ 3.3 Scope.

This section applies to:

- (a) Any combination product, or
- (b) Any product where the agency component with primary jurisdiction is unclear or in dispute.

§ 3.4 Designated agency component.

(a) To designate the agency component with primary jurisdiction for the premarket review and regulation of a combination product, the agency shall determine the primary mode of action of the product. Where the primary mode of action is that of:

(1) A drug (other than a biological product), the agency component charged with premarket review of drugs shall have primary jurisdiction;

(2) A device, the agency component charged with premarket review of devices shall have primary jurisdiction;

(3) A biological product, the agency component charged with premarket review of biological products shall have primary jurisdiction.

(b) In some situations, it is not possible to determine, with reasonable certainty, which one mode of action will provide a greater contribution than any other mode of action to the overall therapeutic effects of the combination product. In such a case, the agency will assign the combination product to the agency component that regulates other combination products that present similar questions of safety and effectiveness with regard to the combination product as a whole. When there are no other combination products that present similar questions of safety and effectiveness with regard to the combination product as a whole, the agency will assign the combination product to the agency component with the most expertise related to the most significant safety and effectiveness questions presented by the combination product.

(c) The designation of one agency component as having primary jurisdiction for the premarket review and reg-

ulation of a combination product does not preclude consultations by that component with other agency components or, in appropriate cases, the requirement by FDA of separate applications.

[56 FR 58756, Nov. 21, 1991, as amended at 70 FR 49861, Aug. 25, 2005]

§ 3.5 Procedures for identifying the designated agency component.

(a)(1) The Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, and the Center for Drug Evaluation and Research have entered into agreements clarifying product jurisdictional issues. These guidance documents are on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and are entitled “Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health;” “Intercenter Agreement Between the Center for Devices and Radiological Health and the Center for Biologics Evaluation and Research;” “Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research.” The availability of any amendments to these intercenter agreements will be announced by FEDERAL REGISTER notice.

(2) These guidance documents describe the allocation of responsibility for categories of products or specific products. These intercenter agreements, and any amendments thereto, are nonbinding determinations designed to provide useful guidance to the public.

(3) The sponsor of a premarket application or required investigational filing for a combination or other product covered by these guidance documents may contact the designated agency component identified in the intercenter agreement before submitting an application of premarket review or to confirm coverage and to discuss the application process.

(b) For a combination product not covered by a guidance document or for a product where the agency component with primary jurisdiction is unclear or

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in dispute, the sponsor of an application for premarket review should follow the procedures set forth in §3.7 to request a designation of the agency component with primary jurisdiction before submitting the application.

[56 FR 58756, Nov. 21, 1991, as amended at 68 FR 24879, May 9, 2003]

§3.6 Product jurisdiction officer.

The Office of Combination Products (HFG-3), Food and Drug Administration, 15800 Crabbs Branch Way, suite 200, Rockville, MD 20855, 301-427-1934, e-mail: *combination@fda.gov*, is the designated product jurisdiction officer.

[68 FR 37077, June 23, 2003, as amended at 71 FR 16033, Mar. 30, 2006]

§3.7 Request for designation.

(a) Who should file: the sponsor of:

(1) Any combination product the sponsor believes is not covered by an intercenter agreement; or

(2) Any product where the agency component with primary jurisdiction is unclear or in dispute.

(b) When to file: a sponsor should file a request for designation before filing any application for premarket review, whether an application for marketing approval or a required investigational notice. Sponsors are encouraged to file a request for designation as soon as there is sufficient information for the agency to make a determination.

(c) What to file: an original and two copies of the request for designation must be filed. The request for designation must not exceed 15 pages, including attachments, and must set forth:

(1) The identity of the sponsor, including company name and address, establishment registration number, company contact person and telephone number.

(2) A description of the product, including:

(i) Classification, name of the product and all component products, if applicable;

(ii) Common, generic, or usual name of the product and all component products;

(iii) Proprietary name of the product;

(iv) Identification of any component of the product that already has received premarket approval, is mar-

keted as not being subject to premarket approval, or has received an investigational exemption, the identity of the sponsors, and the status of any discussions or agreements between the sponsors regarding the use of this product as a component of a new combination product.

(v) Chemical, physical, or biological composition;

(vi) Status and brief reports of the results of developmental work, including animal testing;

(vii) Description of the manufacturing processes, including the sources of all components;

(viii) Proposed use or indications;

(ix) Description of all known modes of action, the sponsor's identification of the single mode of action that provides the most important therapeutic action of the product, and the basis for that determination.

(x) Schedule and duration of use;

(xi) Dose and route of administration of drug or biologic;

(xii) Description of related products, including the regulatory status of those related products; and

(xiii) Any other relevant information.

(3) The sponsor's recommendation as to which agency component should have primary jurisdiction based on the mode of action that provides the most important therapeutic action of the combination product. If the sponsor cannot determine with reasonable certainty which mode of action provides the most important therapeutic action of the combination product, the sponsor's recommendation must be based on the assignment algorithm set forth in §3.4(b) and an assessment of the assignment of other combination products the sponsor wishes FDA to consider during the assignment of its combination product.

(d) Where to file: all communications pursuant to this subpart shall be addressed to the attention of the product jurisdiction officer. Such a request, in its mailing cover should be plainly marked "Request for Designation." Concurrent submissions of electronic