

## Food and Drug Administration, HHS

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### Subpart B [Reserved]

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 360c-360f, 360h-360j, 360gg-360ss, 371(a), 379e, 381, 394; 42 U.S.C. 216, 262.

SOURCE: 56 FR 58756, Nov. 21, 1991, unless otherwise noted.

### Subpart A—Assignment of Agency Component for Review of Premarket Applications

#### § 3.1 Purpose.

This regulation relates to agency management and organization and has two purposes. The first is to implement section 503(g) of the act, as added by section 16 of the Safe Medical Devices Act of 1990 (Public Law 101-629) and amended by section 204 of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107-250), by specifying 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 and a device; a device and a biological; a biological and a drug; or a drug, a device and a biological. This determination will eliminate, in most cases, the need to receive approvals from more than one FDA component for such combination products. The second purpose of this regulation is to enhance the efficiency of agency management and operations by providing procedures for determining which agency component will have primary jurisdiction for any drug, device, or biological product where such jurisdiction is unclear or in dispute. Nothing in this section prevents FDA from using any agency resources it deems necessary to ensure adequate review of the safety and effectiveness of any product, or the substan-

tial equivalence of any device to a predicate device.

[56 FR 58756, Nov. 21, 1991, as amended by 68 FR 37077, June 23, 2003]

#### § 3.2 Definitions.

For the purpose of this part:

(a) *Act* means the Federal Food, Drug, and Cosmetic Act.

(b) *Agency component* means the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, the Center for Drug Evaluation and Research, or alternative organizational component of the agency.

(c) *Applicant* means any person who submits or plans to submit an application to the Food and Drug Administration for premarket review. For purposes of this section, the terms “sponsor” and “applicant” have the same meaning.

(d) *Biological product* has the meaning given the term in section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

(e) *Combination product* includes:

(1) A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity;

(2) Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;

(3) A drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or

(4) Any investigational drug, device, or biological product packaged separately that according to its proposed

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labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

(f) *Device* has the meaning given the term in section 201(h) of the act.

(g) *Drug* has the meaning given the term in section 201(g)(1) of the act.

(h) *FDA* means Food and Drug Administration.

(i) *Letter of designation* means the written notice issued by the product jurisdiction officer specifying the agency component with primary jurisdiction for a combination product.

(j) *Letter of request* means an applicant's written submission to the product jurisdiction officer seeking the designation of the agency component with primary jurisdiction.

(k) *Premarket review* includes the examination of data and information in an application for premarket review described in sections 505, 510(k), 513(f), 515, or 520(g) or 520(l) of the act or section 351 of the Public Health Service Act of data and information contained in any investigational new drug (IND) application, investigational device exemption (IDE), new drug application (NDA), biologics license application, device premarket notification, device reclassification petition, and premarket approval application (PMA).

(l) *Product* means any article that contains any drug as defined in section 201(g)(1) of the act; any device as defined in section 201(h) of the act; or any biologic as defined in section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

(m) *Product jurisdiction officer* is the person or persons responsible for designating the component of FDA with primary jurisdiction for the premarket review and regulation of a combination product or any product requiring a jurisdictional designation under this part.

(n) *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]

### §3.3 Scope.

This section applies to:

- (a) Any combination product, or

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

### §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