(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) *Mode of action* is the means by which a product achieves an intended therapeutic effect or action. For purposes of this definition, ''therapeutic'' action or effect includes any effect or action of the combination product intended to diagnose, cure, mitigate, treat, or prevent disease, or affect the structure or any function of the body. When making assignments of combination products under this part, the agency will consider three types of mode of action: The actions provided by a biological product, a device, and a drug. Because combination products are comprised of more than one type of regulated article (biological product, device, or drug), and each constituent part contributes a biological product, device, or drug mode of action, combination products will typically have more than one identifiable mode of action.

(1) A constituent part has a biological product mode of action if it acts by means of a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product applicable to the prevention, treatment, or cure of a disease or condition of human beings, as described in section 351(i) of the Public Health Service Act.

(2) A constituent part has a device mode of action if it meets the definition of device contained in section 201(h)(1) to (h)(3) of the act, it does not have a biological product mode of action, and it does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and is not dependent upon being metabolized for the achievement of its primary intended purposes.

(3) A constituent part has a drug mode of action if it meets the definition of drug contained in section 201(g)(1) of the act and it does not have a biological product or device mode of action.

(l) *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).

(m) *Primary mode of action* is the single mode of action of a combination product that provides the most important therapeutic action of the combination product. The most important therapeutic action is the mode of action expected to make the greatest contribution to the overall intended therapeutic effects of the combination product.

(n) *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)).

(o) *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.

(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 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.

[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 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 (Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5129, Silver Spring, MD 20993–0002, 301–796–8930,, 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; 75 FR 13678, Mar. 23, 2010]