

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 ac-

tion 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