§ 3.2 Definitions.

For the purpose of this part:
(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 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) 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.


§ 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