§ 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. 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.