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21 U.S. Code § 379g

Definitions

For purposes of this subpart:

(1) The term "human drug application" means an application for—

(A) approval of a new drug submitted under section 355(b) of this title, or

(B) licensure of a biological product under subsection (a) of section 262 of title 42.

Such term does not include a supplement to such an application, does not include an application with respect to whole blood or a blood component for transfusion, does not include an application with respect to a bovine blood product for topical application licensed before September 1, 1992, does not include an application with respect to an allergenic extract product licensed before October 1, 2022, does not include an application with respect to a standardized allergenic extract product submitted pursuant to a notification to the applicant from the Secretary regarding the existence of a potency test that measures the allergenic activity of an allergenic extract product licensed by the applicant before October 1, 2022, does not include an application with respect to an in vitro diagnostic biologic product licensed under section 262 of title 42, does not include an application with respect to a large volume parenteral drug product approved before September 1, 1992, does not include an application for a licensure of a biological product for further manufacturing use only, and does not include an application or supplement submitted by a State or Federal Government entity for a drug that is not distributed commercially. Such term does include an application for licensure, as described in subparagraph (B), of a large volume biological product intended for single dose injection for intravenous use or infusion.

(2) The term "supplement" means a request to the Secretary to approve a change in a human drug application which has been approved.

(3)

(A) The term "prescription drug product" means a specific strength or potency of a drug in final dosage form —

(i) for which a human drug application has been approved,

(ii) which may be dispensed only under prescription pursuant to section 353(b) of this title, and

(iii) which is on the list of products described in section 355(j)(7)(A) of this title (not including the discontinued section of such list) or is on a list created and maintained by the Secretary of products approved under human drug applications under section 262 of title 42 (not including the discontinued section of such list).

(B) Such term does not include whole blood or a blood component for transfusion, does not include a bovine blood product for topical application licensed before September 1, 1992, an allergenic extract product licensed before October 1, 2022, a standardized allergenic extract product submitted pursuant to a notification to the applicant from the Secretary regarding the existence of a potency test that measures the allergenic activity of an allergenic extract product licensed by the applicant before October 1, 2022, or an in

vitro diagnostic biologic product licensed under section 262 of title 42. Such term does not include a biological product that is licensed for further manufacturing use only, and does not include a drug that is not distributed commercially and is the subject of an application or supplement submitted by a State or Federal Government entity. Such term does include a large volume biological product intended for single dose injection for intravenous use or infusion.

(C)

(i) If a written request to place a product in the discontinued section of either of the lists referenced in subparagraph (A)(iii) is submitted to the Secretary on behalf of an applicant, and the request identifies the date the product is, or will be, withdrawn from sale, then for purposes of assessing the prescription drug program fee under section 379h(a)(2) of this title, the Secretary shall consider such product to have been included in the discontinued section on the later of—

(I) the date such request was received; or

(II) if the product will be withdrawn from sale on a future date, such future date when the product is withdrawn from sale.

(ii) For purposes of this subparagraph, a product shall be considered withdrawn from sale once the applicant has ceased its own distribution of the product, whether or not the applicant has ordered recall of all previously distributed lots of the product, except that a routine, temporary interruption in supply shall not render a product withdrawn from sale.