
21 U.S. Code § 379j-51

Definitions

For purposes of this subpart:

- (1) The term “adjustment factor” applicable to a fiscal year is the Consumer Price Index for urban consumers (Washington-Arlington-Alexandria, DC-VA-MD-WV; Not Seasonally Adjusted; All items) for September of the preceding fiscal year divided by such Index for September 2011.
- (2) The term “affiliate” means a business entity that has a relationship with a second business entity if, directly or indirectly—
 - (A) one business entity controls, or has the power to control, the other business entity; or
 - (B) a third party controls, or has power to control, both of the business entities.
- (3) The term “biosimilar biological product” means a specific strength of a biological product in final dosage form for which a biosimilar biological product application has been approved.
- (4)
 - (A) Subject to subparagraph (B), the term “biosimilar biological product application” means an application for licensure of a biological product under section 262(k) of title 42.
 - (B) Such term does not include—
 - (i) a supplement to such an application;
 - (ii) an application filed under section 262(k) of title 42 that cites as the reference product a bovine blood product for topical application licensed before September 1, 1992, or a large volume parenteral drug product approved before such date;
 - (iii) an application filed under section 262(k) of title 42 with respect to—
 - (I) whole blood or a blood component for transfusion;
 - (II) an in vitro diagnostic biological product; or
 - (III) a biological product for further manufacturing use only; or
 - (iv) an application for licensure under section 262(k) of title 42 that is submitted by a State or Federal Government entity for a product that is not distributed commercially.

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