Subtitle B--Federal Trade Commission Review
As amended by
"Patient Right to Know Drug Prices Act"
(Public Law No. 115-263) on October 10, 2018 (**marked in red**)
&
"SUPPORT for Patients and Communities Act"
(Public Law No. 115-271) on October 24, 2018 (**marked in blue**)

SEC. 1111. <<NOTE: 21 USC 355 note.>> DEFINITIONS.

In this subtitle:

(1) ANDA.--The term 'ANDA' means an abbreviated drug application, as defined under section 201(aa) of the Federal Food, Drug, and Cosmetic Act.

(2) Assistant attorney general.--The term 'Assistant Attorney General' means the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice.

(3) BIOSIMILAR BIOLOGICAL PRODUCT.—The term 'biosimilar biological product' means a biological product for which a biosimilar biological product application~~an application~~ under section 351(k) of the Public Health Service Act is approved.

(4) BIOSIMILAR BIOLOGICAL PRODUCT APPLICANT.—The term 'biosimilar biological product applicant' means a person who has filed or received approval for a biosimilar biological product application under section 351(k) of the Public Health Service Act.

(5) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION.—The term 'biosimilar biological product application' means an application under section 351(k) of the Public Health Service Act for licensure of a biological product as biosimilar to, or interchangeable with, a reference product~~for licensure of a biological product under section 351(k) of the Public Health Service Act~~.

(~~3~~6) Brand name drug.--The term 'brand name drug' means a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, including an application referred to in section 505(b)(2) of such Act or a biological product for which an application is approved under section 351(a) of the Public Health Service Act.

(~~4~~7) Brand name drug company.--The term 'brand name drug Company' means the party that holds the approved application referred to in paragraph (~~3~~6) for a brand name drug that is a listed drug in an ANDA or a reference product in a biosimilar biological product application, or a party that is the owner of a patent for which information is submitted for such drug under subsection (b) or (c) of section 505 of the Federal Food, Drug, and Cosmetic Act or the owner, or exclusive licensee, of a patent included in a list provided under section 351(l)(3) of the Public Health Service Act~~or under section 351(a) of the Public Health Service Act~~.

(~~5~~8) Commission.--The term 'Commission' means the Federal Trade Commission.

(~~6~~9) Generic drug.--The term 'generic drug' means a drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act is approved.

(~~7~~10) Generic drug applicant.--The term 'generic drug Applicant' means a person who has filed or received approval for an ANDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act.

(~~8~~11) Listed drug.--The term 'listed drug' means a brand name drug that is listed under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act.

(12) REFERENCE PRODUCT.—The term 'reference product' has the meaning given such term in section 351(i)~~means a brand name drug for which a license is in effect under section 351(a) of the Public Health Service Act~~.

SEC. 1112. <<NOTE: 21 USC 355 note.>> NOTIFICATION OF AGREEMENTS.

(a) Agreement With Brand Name Drug Company.--

(1) Requirement.--A generic drug applicant that has submitted an ANDA containing a certification under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act or a biosimilar biological product applicant who has submitted a biosimilar biological product application ~~for which a statement under section 351(l)(3)(B)(ii)(I) of the Public Health Service Act has been provided~~ and a brand name drug company that enter into an agreement described in paragraph (2) shall each file the agreement in accordance with subsection (c). The agreement shall be filed prior to the date of the first commercial marketing of the generic drug that is the subject of the ANDA or the biosimilar biological product that is the subject of the biosimilar biological product application, as applicable.

(2) Subject matter of agreement.--An agreement described in this paragraph between a generic drug applicant or a biosimilar biological product applicant and a ~~brand name~~listed drug company is an agreement regarding—

(A) the manufacture, marketing, or sale of the brand name drug that is the listed drug in the ANDA or the reference product in the biosimilar biological product application involved;

(B) the manufacture, marketing, or sale of the generic drug for which the ANDA was submitted or of the biosimilar biological product for which the biosimilar biological product application was submitted; or

(C) (i) the 180-day period referred to in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act as it applies to such ANDA or to any other ANDA based on the same brand name drug; or

(ii) any of the time periods referred to in section 351(k)(6) of the Public Health Service Act as such period applies to such biosimilar biological product application or to any other biosimilar biological product application based on the same reference product. ~~the 1-year period referred to in section 351(k)(6)(A) of the Public Health Service Act as it applies to such biosimilar biological product application or to any other biosimilar biological product application based on the same brand name drug~~.

(b) Agreement With Another Generic Drug Applicant Or Biosimilar Biological Product Applicant.--

(1) Requirement.~~—~~—

(A) GENERIC DRUGS. - A generic drug applicant that has submitted an ANDA containing a certification under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act with respect to a listed drug and another generic drug applicant that has submitted an ANDA containing such a certification for the same listed drug shall each file the agreement in accordance with subsection (c). The agreement shall be filed prior to the date of the first commercial marketing of either of the generic drugs for which such ANDAs were submitted.

(B) BIOSIMILAR BIOLOGICAL PRODUCTS.—A biosimilar biological product applicant that has submitted a biosimilar biological product application for which a statement undersection 351(l)(3)(B)(ii)(I) of the Public Health Service Act has been provided with respect to a reference product and another biosimilar biological product applicant that has submitted a biosimilar biological product application for which such a statement for the same reference product has been provided shall each file the agreement in accordance with subsection (c). The agreement shall be filed prior to the date of the first commercial marketing of either of the biosimilar biological products for which such biosimilar biological product applications were submitted.

(2) Subject matter of agreement.--An agreement described in this paragraph ~~between two generic drug applicants is an agreement~~is, as applicable, an agreement between 2 or more generic drug applicants~~2 generic drug applicants~~ regarding the 180-day period referred to in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act as it applies to the ANDAs with which the agreement is concerned, an agreement between 2 or more biosimilar biological product applicants regarding a time period referred to in section 351(k)(6) of the Public Health Service Act as it applies to the biosimilar biological product, or an agreement between 2 or more biosimilar biological product applicants regarding the manufacture, marketing, or sale of a biosimilar biological product~~, or an agreement between 2 biosimilar biological product applicants regarding the 1-year period referred to in section 351(k)(6)(A) of the Public Health Service Act as it applies to the biosimilar biological product applications with which the agreement is concerned~~.

(c) Filing.--

(1) Agreement.--The parties that are required in subsection (a) or (b) to file an agreement in accordance with this subsection shall file with the Assistant Attorney General and the Commission the text of any such agreement, except that such parties are not required to file an agreement that solely concerns--

(A) purchase orders for raw material supplies;

(B) equipment and facility contracts;

(C) employment or consulting contracts; or

(D) packaging and labeling contracts.

(2) Other agreements.--The parties that are required in subsection (a) or (b) to file an agreement in accordance with this subsection shall file with the Assistant Attorney General and the Commission the text of any agreements between the parties that are not described in such subsections and are contingent upon, provide a contingent condition for, were entered into within 30 days of, or are otherwise related to an agreement that is required in subsection (a) or (b) to be filed in accordance with this subsection.

(3) Description.--In the event that any agreement required in subsection (a) or (b) to be filed in accordance with this subsection has not been reduced to text, each of the parties involved shall file written descriptions of such agreement that are sufficient to disclose all the terms and conditions of the agreement

SEC. 1113. <<NOTE: 21 USC 355 note.>> FILING DEADLINES.

Any filing required under section 1112 shall be filed with the Assistant Attorney General and the Commission not later than 10 business days after the date the agreements are executed.

SEC. 1114. <<NOTE: 21 USC 355 note.>> DISCLOSURE EXEMPTION.

Any information or documentary material filed with the Assistant Attorney General or the Commission pursuant to this subtitle shall be exempt from disclosure under section 552 of title 5, United States Code, and no such information or documentary material may be made public, except as may be relevant to any administrative or judicial action or proceeding. Nothing in this section is intended to prevent disclosure to either body of the Congress or to any duly authorized committee or subcommittee of the Congress.

SEC. 1115. <<NOTE: 21 USC 355 note.>> ENFORCEMENT.

(a) Civil Penalty.--Any brand name drug company, generic drug applicant, or biosimilar biological product applicant ~~or generic drug applicant~~ which fails to comply with any provision of this subtitle shall be liable for a civil penalty of not more than $11,000, for each day during which such entity is in violation of this subtitle. Such penalty may be recovered in a civil action brought by the United States, or brought by the Commission in accordance with the procedures established in section 16(a)(1) of the Federal Trade Commission Act (15 U.S.C. 56(a)).

(b) Compliance and Equitable Relief.--If any brand name drug company, generic drug applicant, or biosimilar biological product applicant ~~or generic drug applicant~~ fails to comply with any provision of this subtitle, the United States district court may order compliance, and may grant such other equitable relief as the court in its discretion determines necessary or appropriate, upon application of the Assistant Attorney General or the Commission.

SEC. 1116. <<NOTE: 21 USC 355 note.>> RULEMAKING.

The Commission, with the concurrence of the Assistant Attorney General and by rule in accordance with section 553 of title 5, United States Code, consistent with the purposes of this subtitle—

(1) may define the terms used in this subtitle;

(2) may exempt classes of persons or agreements from the requirements of this subtitle; and

(3) may prescribe such other rules as may be necessary and appropriate to carry out the purposes of this subtitle.

SEC. 1117. <<NOTE: 21 USC 355 note.>> SAVINGS CLAUSE.

Any action taken by the Assistant Attorney General or the Commission, or any failure of the Assistant Attorney General or the Commission to take action, under this subtitle shall not at any time bar any proceeding or any action with respect to any agreement between a brand name drug company and a generic drug applicant or a biosimilar biological product applicant, any agreement between generic drug applicants, or any agreement between biosimilar biological product applicants~~, or any agreement between generic drug applicants~~, under any other provision of law, nor shall any filing under this subtitle constitute or create a presumption of any violation of any competition laws.