Amend the 180-Day Exclusivity Provisions to Encourage Timely Marketing of First Generics

Draft Legislative Text

SEC. 1. 180-DAY EXCLUSIVITY PERIOD.

Section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iv)) is amended—

(1) in subclause (I)—

(A) by inserting "and has commenced commercial marketing" after "an application containing such a certification"; and

(B) by striking "the date of the first commercial marketing" and inserting "the earliest date of first commercial marketing"; and

(2) in subclause (II)(aa), by striking "ending on the day" and all that follows through the period and inserting "starting on the earliest date of first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant. During the 180-day exclusivity period, an application submitted by an applicant other than a first applicant may not be made effective. The 180-day exclusivity period does not affect an application submitted by an applicant other than a first applicant that received effective approval before the period started."

Edits redlined in the existing provision:

(iv) 180-day exclusivity period.-

(I) Effectiveness of application.-Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification and has commenced commercial marketing, the application shall be made effective on the date that is 180 days after the earliest date of ~~the~~ first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

(II) Definitions.-In this paragraph:

(aa) 180-day exclusivity period.-The term "180-day exclusivity period" means the 180-day period starting on the earliest date of first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant. During the 180-day exclusivity period, an application submitted by an applicant other than a first applicant may not be made effective. The 180-day exclusivity period does not affect an application submitted by an applicant other than a first applicant that received effective approval before the period started.~~ending on the day before the date on which an application~~ that was ~~submitted by an applicant other than a first applicant and that did not receive effective approval before a first applicant commenced commercial marketing could become effective under this clause~~.

(bb) First applicant.-As used in this subsection, the term "first applicant" means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug,

submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.

(cc) Substantially complete application.-As used in this subsection, the term "substantially complete application" means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

(dd) Tentative approval.-

(AA) In general.-The term "tentative approval" means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (F) or section 355a of this title, or there is a 7-year period of exclusivity for the listed drug under section 360cc of this title.

(BB) Limitation.-A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

SEC. 2. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD; FAILURE TO MARKET; FAILURE TO OBTAIN TENTATIVE APPROVAL.

Section 505(j)(5)(D)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)) is amended—

(1) by striking subclauses (I) and (IV); and

(2) by redesignating subclauses (II), (III), (V), and (VI) as subclauses (I) through (IV), respectively.

Edits redlined in the existing provision:

~~(I) Failure to market.-The first applicant fails to market the drug by the later of-~~

~~(aa) the earlier of the date that is-~~

~~(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or~~

~~(BB) 30 months after the date of submission of the application of the first applicant; or~~

~~(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:~~

~~(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.~~

~~(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.~~

~~(CC) The patent information submitted under subsection (b) or (c) is withdrawn by the holder of the application approved under subsection (b).~~

(I~~I~~) Withdrawal of application.-The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).

(II~~I~~) Amendment of certification.-The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

~~(IV) Failure to obtain tentative approval.-The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.~~

(III~~V~~) Agreement with another applicant, the listed drug application holder, or a patent owner.-The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 12 of title 15, except that the term includes section 45 of title 15 to the extent that that section applies to unfair methods of competition).

(IV~~I~~) Expiration of all patents.-All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.