MEDICARE PRESCRIPTION DRUG AND IMPROVEMENT ACT REQUIRES DRUG COMPANIES TO FILE CERTAIN AGREEMENTS WITH THE FEDERAL TRADE COMMISSION AND U.S. DEPARTMENT OF JUSTICE

Effective Dates of Filing Requirements:
January 7, 2004 for certain agreements regarding drug products
October 10, 2018 for certain agreements regarding biological products

Section 1112 of Subtitle B ("Federal Trade Commission Review") of Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (21 U.S.C. § 355 note), as amended, requires that brand-name drug manufacturers, generic drug applicants, and biosimilar biological product applicants file certain agreements with the Federal Trade Commission and the Department of Justice (the Agencies) within 10 business days of execution of the agreement. This requirement became effective on January 7, 2004, and was extended to biological products on October 10, 2018.

The Agencies will track the filing of these agreements and may propose rules as necessary and appropriate to carry out the purposes of this subtitle.

Agreements That Must Be Filed

Sections 1112(a) and (b) identify four categories of agreements that must be filed with the Agencies. Under section 1112(c), agreements that are contingent upon, provide a contingent condition for, were entered into within 30 days of,[1] or are otherwise related to an agreement under these four categories must also be filed by the parties involved.

1. Generic-Brand Agreements: Section 1112(a) requires a generic drug applicant that has submitted an Abbreviated New Drug Application (ANDA) containing a certification under section 505 (j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act (FFDCA) and a brand name company[2] that enter into an agreement regarding:

   (A) the manufacture, marketing, or sale of a brand name drug that is listed in the ANDA involved;

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[1] The requirement to file any agreement entered "within 30 days of" an agreement under subsection 1112(a) or (b) was added in an October 24, 2018 amendment.

[2] Section 1111(7) defines a "brand name drug company" to mean the party that holds the approved application of a "brand name drug" 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 FFDCA.

Section 1111(6) defines a "brand name drug" to mean a drug for which an application is approved under Section 505(c) of the FFDCA, including an application referred to in section 505(b)(2) of the FFDCA, or a biological product for which an application is approved under section 351 (a) of the Public Health Service Act.

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

(C) the 180-day period referred to in section 505(j)(5)(B)(iv) of the FFDCA as it applies to such ANDA or to any other ANDA based on the same brand name drug

to file the agreement with the Agencies, subject to the requirement of section 1112(c). Section 1112(a)(1) provides that "[t]he agreement shall be filed prior to the date of the first commercial marketing of the generic drug that is the subject of the ANDA."

2. Biological Product Agreements: Section 1112(a), as amended, further requires a biosimilar biological product applicant and a brand name drug company that enter into an agreement regarding:

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

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

(C) 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

to file the agreement with the Agencies, subject to the requirements of section 1112(c). Section 1112(a)(1) provides that the "[t]he agreement shall be filed prior to the date of the first commercial marketing of . . . the biosimilar biological product that is the subject of the biosimilar biological product application, as applicable."

3. Generic-Generic Agreements: Section 1112(b) requires a generic drug applicant that has submitted an ANDA containing a certification under section 205(j)(2)(A)(vii)(IV) of the FFDCA 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 that enter into an agreement related to the 180-day period referred to in section 505(j)(5)(B)(iv) of the FFDCA, to file the agreement with the Agencies, subject to the requirements of section 1112(c). Section 1112(b)(11) provides that "[t]he 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."

4. Biosimilar-Biosimilar Agreements: Section 1112(b), as amended, further requires that biosimilar biological product applicants shall each file any agreement that (1) references the same reference drug product for which each has filed a biological product application and (2) regards either (a) 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 (b) the manufacture, marketing, or sale of a biosimilar biological product. The agreements 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.

Filing of Agreements

Section 1112(c) governs the filing of the agreements with the Agencies:

1. Section 1112(c)(1) requires that parties required to file an agreement under section 1112 (a) or (b) must file the text of such agreements with the Agencies.

2. Section 1112(c)(1) states that the parties subject to section 1112(a) or (b) are not required to file an agreement that solely concerns:

   (A) purchase orders for raw materials;

   (B) equipment and facility contracts;

   (C) employment or consulting contracts; or

   (D) packaging and labeling contracts.

3. Section 1112(c)(2) requires parties also to file the text of any agreements between the parties that are not described in section 1112(a) or (b) 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 to be filed under section 1112(a) or (b).

4. Section 1112(c)(3) requires that in the event that any agreement required to be filed under section 1112(a) or (b) 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.

Filing Deadlines

Section 1113 provides that "[a]ny filing required under section 1112 shall be filed with [the Agencies] not later than 10 business days after the date the agreements are executed." If the agreement allows commercial marketing of a generic drug that is the subject of the ANDA within 10 business days of the agreement's execution, the agreement shall be filed prior to the date of the first commercial marketing of the generic drug, as required by sections 1112(a)(1) and 1112(b)(1).

Filing Procedure

The parties required to file agreements pursuant to sections 1112(a) and (b) are requested to file electronic copies of the agreement with the Federal Trade Commission and the Department of Justice. The filings should include the appropriate cover sheet and be emailed to mma@ftc.gov

(Federal Trade Commission) and mma@usdoj.gov (Department of Justice). All documents submitted must be in a searchable PDF format.

Enforcement

Section 1115(a) provides that "[a]ny brand name drug company, generic drug applicant, or biosimilar biological product applicant which fails to comply with any provision of this subtitle shall be liable for a civil penalty . . . for each day during which such entity is in violation of this subtitle." The maximum amount of civil penalty, as adjusted, is provided in 16 CFR § 1.98(n). Further, section 1115(b) states that, upon application of the Assistant Attorney General or the Federal Trade Commission, "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[.]"

For further information, contact Bradley S. Albert, Federal Trade Commission, (202) 326-3670, or Suzanne Morris, Department of Justice, (202) 514-2558.