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 Date of the Act's Filing Requirements: Wednesday, January 7, 2004

Section 1112 of Subtitle B ("Federal Trade Commission Review") of Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the Act) requires that brand-name drug manufacturers and generic drug applicants file certain agreements with the Federal Trade Commission and the Assistant Attorney General (the Antitrust Agencies) within 10 business days of execution of the agreement. This requirement covers agreements executed on or after January 7, 2004.

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

Agreements That Must Be Filed

Section 1112 identifies the two categories of agreements that if executed on or after January 7, 2004, are to be filed with the Antitrust Agencies.

1. Section 1112(a) 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 drug company[1] that enter into an agreement regarding

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

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[1] Section 1111(4) 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(3) 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.

2. Section 1112(b) Generic-Generic Agreements: Section 1112(b) requires a generic drug applicant that has submitted an ANDA containing a certification under Section 505(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 Antitrust Agencies, subject to the requirements of Section 1112(c). Section 1112(b)(1) 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."

Filing of Agreements

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

1. Section 1112(c)(1) states that 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.

2. 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, or are otherwise related to an agreement that is required to be filed under Section 1112(a) or (b).

3. 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 Antitrust Authorities] 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 Copies and Addresses

The parties required to file agreements pursuant to Sections 1112(a) and 1112(b) are requested to file two (2) copies of the agreement with the Federal Trade Commission and two (2) copies of the agreement with the Department of Justice at the following addresses:

Premerger Notification Office
Bureau of Competition, Room 303
Federal Trade Commission
600 Pennsylvania Ave, NW
Washington, DC 20580

Director of Operations and Civil Enforcement
Antitrust Division, Department of Justice
Patrick Henry Building
601 D Street, NW, Room #10013
Washington, DC 20530
(For FEDEX airbills to the Department of Justice, do not use the 20530 zip code, use zip code 20004)

The filing should include a transmittal letter or memorandum indicating clearly on the first page the subsection of Section 1112 under which the agreement is being filed. For example, "Filing Pursuant to Section 1112(a)" or "Filing Pursuant to Section 1112(b)" could be used in the subject line of the transmittal letter or memorandum.

Enforcement

Section 1115(a) of the Act provides that "[a]ny brand name drug company 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 [Federal Trade] Commission[.]"

Section 1115(b) of the Act provides that "[i]f any brand name drug company 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 [Federal Trade] Commission."

For Further Information: Contact Brad Albert, Federal Trade Commission (202) 326-3670; Michael Wroblewski, Federal Trade Commission (202) 326-2155; or Elaine Gibbs, Department of Justice (202) 514-2558.