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

(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 requirements 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 to enter in 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; and

(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

product or (b) the manufacture, marketing, or sale of a biosimilar biological product. 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.

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).6.7Tw 2.5