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 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 Antitrust 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."

Filings of Agreements

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

1. 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.

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)