Frequently Asked Questions About Filing Agreements with the FTC Pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires drug companies to file certain agreements with the Federal Trade Commission and the U.S. Department of Justice. Information about what types of agreements must be filed, filing deadlines, and where to file is set forth at https://www.ftc.gov/tips-advice/competition-guidance/industry-guidance/health-care/pharmaceutical-agreement-filings.

Below are answers to some frequently asked questions about the FTC's process and procedures.

1. How do I file agreements with the FTC and the DOJ?

Effective June 17, 2019, parties should email all MMA-related filings to mma@ftc.gov and mma@usdoj.gov.

2. May I file supplementary materials in addition to the agreement?

You may submit anything you believe will assist the agencies in evaluating the agreement.

3. Who at the FTC reviews the filing?

The agreements are reviewed by the FTC Bureau of Competition's Health Care Division.

4. May I discuss the agreement with FTC staff before filing?

FTC staff is willing to discuss issues with parties in advance of their filing an agreement.

5. How long will the FTC's review take?

There is no prescribed timetable for the FTC's review. If you want to ask about the status of FTC review of your agreement, you may contact Bradley S. Albert at (202) 326-3670. A provision in the agreement concerning a timetable for FTC review does not bind the agency.

6. When will I be told if my agreement has been approved?

The FTC neither approves nor denies approval to filed agreements.

A lack of action by the Commission or its staff with respect to a filed agreement does not signify an implicit approval of the agreement or a lack of antitrust concern. In addition, the MMA expressly provides that FTC inaction concerning a filed agreement is not a bar to any later antitrust action.[1]

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[1] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1117 ("Any action taken by the Assistant Attorney General or the Commission, or any failure of the Assistant Attorney General or the Commission to take action, under this subtitle shall not at any time bar any proceeding or any action with respect to any agreement between a

Any suggestions by drug companies to courts or others that FTC inaction indicates that the agreement presents no antitrust problem would be inaccurate and improper.

7. Can I go forward with the agreement after it has been filed, even if I have not heard from the FTC?

Yes. Unlike the merger review process under the Hart-Scott-Rodino Act, there is no waiting period.

8. Do I need to file an agreement resolving a proceeding before the Patent and Trademark Office's Patent Trial and Appeal Board (PTAB), such as an *inter partes* review (IPR)?

The Act's filing requirement is not limited to settlement of patent litigation. It focuses on the substance of an agreement between a brand and generic company. Thus, to the extent an agreement between a brand and generic company resolves a PTAB proceeding and relates to substantive areas outlined in the MMA—such as the manufacture, marketing, or sale of the generic drug or biosimilar—the agreement must be filed.

9. Do I need to file a joint stipulation of dismissal when there is no related settlement or license contract?

A joint stipulated dismissal is an agreement between the parties to the litigation and, to the extent it relates to substantive areas outlined in the MMA, must be filed. The FTC provided guidance on this topic in 2011.

10. Do I need to file an agreement involving biological products?

Yes. Effective October 10, 2018, parties are required to file certain agreements involving biologic and biosimilar products.[2]

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brand name drug company and a generic drug applicant or a biosimilar biological product applicant, or any agreement between generic drug applicants, or any agreement between biosimilar biological product applicants under any other provision of law . . . .").

[2] *See* MMA Pharmaceutical Filing Instructions (June 6, 2019).