

## **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/enforcement/premerger-notification-program/medicare-act-filings>. Below are answers to some frequently asked questions about the FTC's process and procedures.

### **1. May I file supplementary materials in addition to the agreement?**

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

### **2. Who at the FTC reviews the filing?**

The agreements are referred to the FTC Bureau of Competition's Health Care Division for review.

### **3. 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.

### **4. 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 an agreement setting a timetable for FTC review does not bind the agency.

### **5. 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.<sup>1</sup>

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.

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<sup>1</sup> 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 brand name drug company and a generic drug applicant, or any agreement between generic drug applicants, under any other provision of law . . .”).

**6. 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.