

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 <http://www.ftc.gov/os/2004/01/040106pharmrules.pdf>. 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 that 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 Division of Health Care Services and Products for review.

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

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

4. Will I be told if my agreement has been approved? If so, when?

The FTC neither approves nor denies approval to the filed agreements. As a general matter, FTC staff members will contact you only if they need more information to aid their review.

5. 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.

6. 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.