

Frequently Asked Questions About Filing Agreements with the FTC Pursuant to the Medicare Prescription Drug, Iideadlines, and where to file is set forth at

<https://www.ftc.gov/tipsadvice/competition/guidance/industryguidance/healthcare/pharmaceuticalagreementfilings>.

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?

File the agreement with the FTC and the DOJ at <https://www.ftc.gov/ftcdotgov>.

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

Yes, you may file supplementary materials in addition to the agreement.

3. Who at the FTC reviews the filing?

The filing is reviewed by the FTC staff.

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

Yes, you may discuss the agreement with FTC staff before filing.

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

The FTC’s review of a filing typically takes 30 to 60 days, depending on the complexity of the agreement and the volume of filings. The review process may be extended if the FTC staff requests additional information or if there are any issues with the filing.

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

Once the FTC staff has reviewed the filing and approved the agreement, you will be notified by email. The approval process typically takes 30 to 60 days, depending on the complexity of the agreement and the volume of filings. The review process may be extended if the FTC staff requests additional information or if there are any issues with the filing.

¹ The FTC staff typically reviews a filing within 30 to 60 days of the filing date. The review process may be extended if the FTC staff requests additional information or if there are any issues with the filing.

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 ~~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 ~~litigation~~ litigation. It focuses on the substance of an agreement ~~between a brae ta~~ between a brae ta