



FEDERAL TRADE COMMISSION COMMENT ON THE FOOD AND DRUG ADMINISTRATION'S REVISED DRAFT GUIDANCE ON CITIZEN PETITIONS

I. Introduction

The Federal Trade Commission¹ submits the following response to the Food and Drug Administration's ("FDA") call for public comments to its revised draft guidance for industry entitled, *Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act* (hereinafter "Revised Draft Guidance").² The Revised Draft Guidance, which is part of the FDA's *Drug Competition Action Plan*,³ seeks to deter pharmaceutical companies from abusing the FDA's citizen-petition process to delay generic drug and biosimilars approvals and therefore delay generic competition. In the Revised Draft Guidance, the FDA:

- Reiterates its authority to deny a petition that does not raise facially valid scientific or regulatory issues and that was primarily submitted to delay FDA approval of another drug;
- Describes considerations it will use to determine whether a petition was primarily submitted to delay the approval of a competing drug; and
- Discusses actions that the FDA may take once it makes such a determination.

¹ The FTC approved this statement by a vote of 5-0.

² The Revised Draft Guidance and related FDA statement are available at <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM622235.pdf> and <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm622252.htm>.

³ The FDA announced in July 2017 its *Drug Competition Action Plan*, an initiative to "facilitate[e] increased competition in the market for prescription drugs through the approval of lower-cost generic medicines." FDA Statement at <https://www.fda.gov/NewsEvents/Newsroom/FDAVoices/ucm612018.htm>.

Generic competition plays a crucial role in containing rising prescription drug costs. Generic drugs offer consumers and patients therapeutically equivalent alternatives to branded drugs at a significantly reduced cost. The FDA estimates the cost savings from generic drugs approved in 2017 to be \$16 billion in the 12 months following drug approval alone.⁴ The FTC shares the FDA's concerns about patient access to lower-cost generic drugs and biosimilars. Moreover, the FTC has a longstanding interest in sham petitioning and other abuses of government processes that may inhibit competition.⁵ For these reasons, the FTC supports the FDA's efforts to deter abuse of the citizen-petition process.

II. FTC Interest and Experience

The FTC is an independent administrative agency charged by Congress with protecting consumers by enforcing competition and consumer protection laws.⁶ The FTC exercises primary responsibility for federal civil antitrust enforcement in the pharmaceutical industry.⁷ For over twenty years, the FTC has been investigating and litigating cases to protect competition in the prescription drug market.⁸

Of particular relevance to the Revised Draft Guidance, the FTC has investigated complaints of abuses of the FDA citizen-petition process as potential violations of federal antitrust law.⁹ In 2017, the FTC filed a complaint in federal district court charging that Shire ViroPharma, a brand pharmaceutical company, illegally maintained its monopoly power by

⁴ See FDA Report, *Estimating Cost Savings from Generic Drug Approvals In 2017*, <https://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/UCM609808.pdf>.

⁵ See, e.g., *FTC Staff Report: Enforcement Perspectives on the Noerr-Pennington Doctrine* (2006), available at <https://www.ftc.gov/sites/default/files/documents/reports/ftc-staff-report-concerning-enforcement-perspectives-noerr-pennington-doctrine/p013518enfperspectnoerr-penningtondoctrine.pdf>.

⁶ 15 U.S.C. §§ 41-58.

⁷ For a summary of the FTC's antitrust actions in the pharmaceutical industry, see *Fed. Trade Comm'n, Overview of FTC Antitrust Actions in Pharmaceutical Products and Distribution* (2018), https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview_pharma_august_2018.pdf.

⁸ For example, the FTC, on a bipartisan basis, has prioritized ending anticompetitive reverse payment agreements in which a brand drug company pays its potential generic rival to give up its patent challenge and agree not to launch a lower-cost generic product. See, e.g., *FTC v. Actavis*, 570 U.S. 756 (2013); No. 1:09-MD-2084 (N.D. Ga. Jun. 14, 2018); Press Release, *FTC Settlement of Cephalon Pay for Delay Case Ensures \$1.2 Billion in Ill-Gotten Gains Relinquished; Refunds Will Go To Purchasers Affected by Anticompetitive Tactics* (May 28, 2015), <https://www.ftc.gov/news-events/press-releases/2015/05/ftc-settlement-cephalon-pay-delay-case-ensures-12-billion-ill>.

⁹ The FTC also has identified other potentially anticompetitive strategies by pharmaceutical companies to misuse other FDA processes like the FDA's Risk Evaluation and Mitigation Strategies programs. See *Fed. Trade Comm'n Brief as Amicus Curiae, Mylan Pharm., Inc. v. Celgene Corp.*, No. 2:14-CV-2094 (D. N.J. June 17, 2014), <https://www.ftc.gov/policy/advocacy/amicus-briefs/2014/06/mylan-pharmaceuticals-inc-v-celgene-corporation>; and *Fed. Trade Comm'n Brief as Amicus Curiae, Actelion Pharm. Ltd. v. Apotex Inc.*, No. 1:12-cv05743 (D. N.J. Mar. 11, 2013), http://www.ftc.gov/sites/default/files/documents/amicus_briefs/actelionpharmaceuticals-ltd-et-al.v.apotex-inc./130311actelionamicusbrief.pdf.

abusing government processes, including the citizen-petition process.¹⁰ The FTC alleged that Shire ViroPharma filed 43 serial, unsupported petitions with the FDA—along with three lawsuits against the FDA—over a six-year period to obstruct and delay approval of generic versions of its branded drug.¹¹ According to the complaint, Shire ViroPharma petitioned the FDA to apply a testing standard to the generic applications that was more stringent than the standard used to approve its own branded drug.¹² Even after a panel of independent scientific and medical experts unanimously rejected its unsupported arguments, Shire ViroPharma repeated its arguments, the complaint alleged.¹³ The FTC asserted that Shire ViroPharma’s conduct significantly delayed the FDA approval of a generic drug, which cost consumers hundreds of millions of dollars.¹⁴ In March 2018, the federal district court ruled that the FTC’s complaint stated a valid claim that Shire ViroPharma’s repetitive and baseless petitions were sham petitioning and violated the antitrust laws.¹⁵

III. Challenges Facing the FDA

Through the Hatch-Waxman Act, Congress created a carefully balanced regulatory framework facilitating the introduction of lower-cost generic drugs while preserving incentives for innovation.¹⁶ The Hatch-Waxman Act provides, among other things, a mechanism for accelerated approval of generic drugs through an Abbreviated New Drug Application (“ANDA”). With an ANDA, a generic manufacturer may rely on a branded drug’s already-completed safety and efficacy studies after showing that its generic version is bioequivalent to the branded drug.

Despite the tremendous savings to consumers and patients afforded by generic and biosimilars competition, some pharmaceutical companies have employed a variety of strategies—including conduct that violates antitrust laws—to delay generic competition. The citizen-petition process presents one such avenue for innovator companies to abuse government process and to delay generic and biosimilar competition.

¹⁰ *FTC v. Shire ViroPharma*, No. 1:17-cv-00131 (D. Del. Feb. 7, 2017), <https://www.ftc.gov/enforcement/casesproceedings/121-0062/shire-viropharma>.

¹¹ See *FTC v. Shire ViroPharma* Complaint ¶ 1, https://www.ftc.gov/system/files/documents/cases/170216viropharma_unredacted_sealed_complaint_.pdf.

¹² See *id.* at ¶ 126.

¹³ See *id.* at ¶ 1.

¹⁴ See *id.*

¹⁵ The district court nonetheless dismissed the FTC’s complaint on jurisdictional grounds under Section 13(b) of the FTC Act. The FTC has appealed the Section 13(b) ruling to the Third Circuit. *FTC v. Shire ViroPharma*, No. 18-1807 (3d Cir. 2018).

¹⁶ In 2009, Congress enacted analogous legislation to foster competition between and among biologics, biosimilars, and interchangeable biosimilars, entitled the Biologics Price Competition and Innovation Act (“BPCIA”). The BPCIA created an abbreviated regulatory approval process for biosimilars and interchangeables and required the FDA to promulgate guidance implementing the statute.

A citizen petition allows a stakeholder to request the FDA to take action. Pharmaceutical companies often use these petitions to ask the FDA not to approve a generic or biosimilar application unless certain conditions are met. As part of its public health mandate, the FDA reviews each petition. Answering a petition requires significant FDA time and resources. FDA staff must carefully consider the issues raised by the petition. Each response to a petition must be prepared, reviewed, and vetted by staff across the FDA. Although some citizen petitions raise genuine issues for scientific consideration, many petitions do not and are denied for lack of merit.¹⁷

With an eye towards curbing potential citizen-petition abuse, in 2007, Congress enacted Section 505(q) of the Federal Food, Drug, and Cosmetic Act (“Section 505(q)”). Section 505(q) requires the FDA to respond to petitions within a specified timeframe. It also permits the FDA to summarily deny a petition that does not raise facially valid scientific or regulatory issues and that was submitted primarily to delay FDA approval of another drug or biologic. Nevertheless, meeting Section 505(q)’s statutory deadlines has placed a significant resource burden on the FDA and has forced it to redirect resources from other work.¹⁸ Despite Section 505(q), the FDA and other observers have expressed concerns that petitions submitted primarily to delay approval of competing drug products and without valid scientific issues are not being sufficiently discouraged.¹⁹

Revised Draft Guidance: Further Steps toward Curbing Abuses of the Citizen-Petition Process

In the Revised Draft Guidance, the FDA seeks to deter the continuing misuse of the citizen-petition process. While reiterating the FDA’s Section 505(q) authority to summarily deny certain petitions, the Revised Draft Guidance describes considerations that the FDA will use to determine whether a petition was submitted primarily to delay approval of a competing drug.²⁰

¹⁷ See *FDA Prepared Statement Before the House Committee on the Judiciary, Subcommittee on Regulatory Reform, Commercial and Antitrust Law* (July 27, 2017), <https://www.fda.gov/NewsEvents/Testimony/ucm568869.htm>.

¹⁸ See *FDA’s Ninth Annual Report on Delays in Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action for Fiscal Year 2016* (January 2018), <https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ReportsBuletters/UCM605276.pdf>.

¹⁹ See *id.*; see also Robin Feldman, *A Citizen’s Pathway Gone Astray – Delaying Competition from Generic Drugs*, 376 *New Eng. J. Med.* 1499 (2017); Michael A. Carrier, *Citizen Petitions: Long, Late-Filed, and At-Last Denied*, 66 *Am. U. Law Rev.* 305 (2016).

²⁰ The Draft Revised Guidance aligns the FDA’s petition response process pursuant to Section 505(q) with user fee goals. For example, the FDA will consider Section 505(q) to apply to petitions when the relevant application’s user fee goal date is on or before the FDA’s deadline for responding to the petition pursuant to Section 505(q).

Those considerations include:

- The petition was submitted unreasonably long after petitioner learned or knew about the relevant information;
- The petitioner submitted multiple and/or serial petitions;
- The petition was submitted close in time to expiration of known patent or exclusivity;
- The petition's scientific positions were unsupported by data or information;
- The petition was the same or substantially similar to a prior petition to which the FDA had already substantively responded;
- The petitioner had not commented during other opportunities for input;
- The petition requested a standard more onerous or rigorous than the standard applicable to the petitioner's drug product; and
- Other relevant considerations, including the petitioner's history with the FDA.

The Revised Draft Guidance states that this list is not exhaustive and that each case is unique.

The Revised Draft Guidance also discusses actions that the FDA may take once it determines that a petition was submitted primarily to delay competition. For example, the FDA may summarily deny the petition if it does not raise facially valid scientific or regulatory issues. The FDA may state its determination in its petition response that the petition was submitted primarily to delay competition. According to the Revised Draft Guidance, the FDA will include its determination in its annual report on citizen petitions to Congress. Finally, the FDA confirmed its intention to refer to the FTC instances in which the FDA has concluded that the petitions at issue were submitted with the primary purpose of delaying application approvals.

IV. Readiness to Work with the FDA

We share the FDA's concern about abuse of its citizen petition process to delay beneficial, procompetitive generic or biosimilar entry. In fact, FTC staff has commented on the FDA's past efforts to discourage citizen petition abuse.²¹ Despite the FDA's past efforts and the FTC's long-standing interest in combatting pharmaceutical companies' abuse of government

²¹ In 2000, FTC staff commented on an FDA proposed rule aimed at reducing improper and anticompetitive citizen petitions. The comment provided suggestions to the FDA to deter citizen petition misuse, including referring matters to the FTC. See *Comment of the Staff of the Bureau of Competition and of Policy Planning of the Federal Trade Commission*, (March 2, 2000), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-food-and-drug-administration-concerning-citizen-petitions/v000005.pdf.

processes through antitrust enforcement,²² this behavior continues to delay generic entry and burden FDA staff. We commend the FDA's renewed efforts to curb abuse of the citizen petition process and to promote competition.

Furthermore, we stand ready to work closely with the FDA on citizen-petition abuse and other issues that may harm competition. We share a rich history of collaboration with the FDA to improve U.S. consumers' access to affordable drugs. For example, the FTC and FDA have participated in each other's workshops and testified together in front of Congress. In July 2017, we participated in the FDA's public meeting entitled *The Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access*.²³ Then in November 2017, FDA Commissioner Scott Gottlieb gave keynote remarks at the FTC's workshop on *Understanding Competition in Prescription Drug Markets*.²⁴ In addition, the FTC and FDA testified alongside each other in July 2017 before the U.S. House of Representatives Judiciary Committee, Subcommittee on Regulatory Reform, Commercial and Antitrust Law on ways to deter anticompetitive conduct in the pharmaceutical industry and to promote generic competition.²⁵

We look forward to continuing to work with the FDA to address citizen petition abuse as well as any other issue of common concern.

²² See *FTC Testimony Statement before the Committee on Commerce, Science, and Transportation, United States Senate*, (Apr. 23, 2002) at 5, https://www.ftc.gov/sites/default/files/documents/public_statements/prepared-statement-federal-trade-commission-pharmaceutical-industry/pharmtestimony.pdf.

²³ Public meeting materials: <https://www.fda.gov/drugs/newsevents/ucm563986.htm>.

²⁴ Workshop materials: <https://www.ftc.gov/news-events/events-calendar/2017/11/understanding-competition-prescription-drug-markets-entry-supply>.

²⁵ Prepared statements: <https://www.ftc.gov/news-events/press-releases/2017/07/ftc-testifies-house-judiciary-committees-subcommittee-regulatory>; <https://www.fda.gov/NewsEvents/Testimony/ucm568869.htm>.