Report to Congress

Fourteenth Annual Report on Delays in Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action

FY 2021

Required by Section 914 of the Food and Drug Administration Amendments Act of 2007 (Public Law 110-85)

Executive Summary

Section 505(q) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(q)) applies to certain petitions that request that the Food and Drug Administration (FDA or Agency) take any form of action related to a pending drug approval application submitted under section 505(b)(2) or 505(j) of the FD&C Act or to a pending application for licensure of a biological product as biosimilar or interchangeable that is submitted under section 351(k) of the Public Health Service Act. Under section 505(q)(3) of the FD&C Act, FDA is required to submit an annual report to Congress that includes the following information:

- The number of abbreviated new drug applications (ANDAs), 505(b)(2) applications, and 351(k) applications approved during the reporting period;
- The number of such applications that were delayed by 505(q) petitions;
- The number of days by which the applications were delayed; and
- The number of 505(q) petitions that were submitted during the reporting period.

During the fiscal year (FY) 2021 reporting period, FDA approved 679 ANDAs, 38 505(b)(2) applications, and three 351(k) applications. In this reporting period, no approvals for ANDAs, 505(b)(2) applications, or 351(k) applications were delayed because of a 505(q) petition. During FY 2021, FDA received five 505(q) petitions.

In addition, FDA stated in its final guidance on 505(q) petitions published in September 2019, that FDA would highlight, in its annual reports to Congress, FDA's determinations regarding 505(q) petitions that may have been submitted with the primary purpose of delaying the approval of any pending application. During the FY 2021 reporting period, FDA did not conclude that any 505(q) petition was submitted with the primary purpose of delaying the approval of an application.[1]

FDA has reviewed the data regarding the outcomes of 505(q) petitions resolved during FYs 2008 through 2021 (see Table 1 in the report). The number of 505(q) petitions decreased in FY 2021 from the prior fiscal year and the number of 505(q) petitions submitted has trended downward in the past few years. A factor that may have contributed to this decrease is the interpretations of the statute described in the final guidance "*Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act*," issued in September 2019.[2] The guidance describes FDA's current thinking on some of the factors the Agency

[1] FDA received a 505(q) petition on November 8, 2021, and stated in its December 15, 2021, response that the petition appeared to have been submitted for the primary purpose of delay and that it failed to raise valid scientific or regulatory issues. FDA referred this petition to the Federal Trade Commission. See Docket No. FDA-2021-P-1211. However, because this petition was submitted during the FY 2022 reporting period, and not the FY 2021 reporting period, it does not fall within the scope of this current report.

[2] This guidance is available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

generally intends to consider in determining whether a petition was submitted with the primary purpose of delay and describes the added scrutiny regarding the purpose, and the scientific validity, of the requests in 505(q) petitions that FDA intends to apply. The approach described in this guidance may have lessened the impact that FDA review of certain citizen petitions may have on any pending approval actions and helped FDA allocate resources efficiently by changing how 505(q) petitions are prioritized. It is unclear whether the decrease will continue. FDA will continue to monitor these trends in light of FDA's previously expressed concern that section 505(q) of the FD&C Act does not discourage the submission of petitions that are intended primarily to delay the approval of competing drug products and do not raise valid scientific issues. However, the trend does appear to be moving toward submission of fewer citizen petitions that fall under section 505(q).

The statute requires FDA to prioritize 505(q) petitions above other matters, such as petitions raising safety concerns, that may raise important public health concerns. Although FDA has generally met the statutory deadlines for 505(q) petitions, it has done so in part by redirecting efforts that otherwise would have been directed to other work, including responding to other citizen petitions.

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I. Statutory Requirements

The Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110-85) was enacted on September 27, 2007. Section 914 of Title IX of FDAAA took effect on the date of enactment and amended section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355) by adding new subsection (q). The Food and Drug Administration Safety and Innovation Act (FDASIA) was signed into law on July 9, 2012 (Pub. L. 112-144, 126 Stat. 993). Section 1135 of FDASIA amended section 505(q) of the FD&C Act.

Section 505(q) of the FD&C Act applies to certain petitions that request that the Food and Drug Administration (FDA or Agency) take any form of action related to a pending drug approval application submitted under the abbreviated approval pathways described either in section 505(b)(2) or section 505(j) of the FD&C Act or under the abbreviated licensure pathway described in section 351(k) of the Public Health Service Act (PHS Act) for biosimilar and interchangeable biological products.[1] Section 505(q) also governs the manner in which these petitions are treated. Section 505(q)(1)(F) of the FD&C Act governs the time frame for final Agency action on a petition subject to 505(q). Under this provision, FDA shall take final Agency action on such petitions not later than 150 days after the date on which the petition was submitted. Under section 505(q)(3) of the FD&C Act, FDA is required to submit an annual report to Congress.

II. Background

A. Citizen Petitions and Petitions for Stay of Agency Action

A citizen petition is a vehicle that stakeholders outside of FDA can use to ask FDA "to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action" (21 CFR 10.25(a) and 10.30). Under the governing regulations, petitioners can request, in a citizen petition, that the Agency, for example:

- Disapprove a drug product application;
- Add warnings to the labeling of a drug; and/or
- Change products from prescription to over-the-counter (OTC) status.

[1] In this report, an application submitted in accordance with section 505(b)(2) of the FD&C Act is referred to as a *505(b)(2) application,* an application submitted under section 505(j) of the FD&C Act is referred to as an *abbreviated new drug application (ANDA)*, and an application submitted under section 351(k) of the PHS Act is referred to as a *351(k) application*. FDA's Center for Drug Evaluation and Research responds to petitions submitted under section 505(q) of the FD&C Act.

FDA's regulations also provide for the submission of petitions for a "stay of action" to delay the effective date of an administrative action, such as the approval of certain drug applications (see 21 CFR 10.35). In this report, both citizen petitions and petitions for a stay of Agency action will be collectively referred to as *petitions*, and petitions subject to section 505(q) of the FD&C Act will be referred to as *505(q) petitions*.

B. Delays of Approvals

Section 505(q)(1)(A) of the FD&C Act provides:

> The Secretary shall not delay approval of a pending application submitted under subsection (b)(2) or (j) of [section 505 of the FD&C Act] or section 351(k) of the Public Health Service Act because of any request to take any form of action relating to the application, either before or during consideration of the request, unless
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> (i) the request is in writing and is a petition submitted to the Secretary pursuant to section 10.30 or 10.35 of title 21, Code of Federal Regulations (or any successor regulations); and
>
> (ii) the Secretary determines, upon reviewing the petition, that a delay is necessary to protect the public health.
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> Consideration of the petition shall be separate and apart from review and approval of any application.[2]

In section 505(q)(5), the term *application* is defined as an application submitted either under section 505(b)(2) or 505(j) of the FD&C Act or under section 351(k) of the PHS Act, and the term *petition* is defined as a request described in section 505(q)(1)(A)(i) (i.e., a written request submitted in accordance with 21 CFR 10.30 or 10.35).

If FDA determines—based on a petition requesting action on a pending abbreviated new drug application (ANDA), 505(b)(2) application, or 351(k) application—that a delay of approval of a pending application is necessary to protect the public health, FDA is required to provide to the applicant, not later than 30 days after making the determination, the following information:

- Notification that the determination has been made;
- If applicable, any clarification or additional data that the applicant should submit to the petition docket to allow FDA to review the petition promptly; and

[2] This sentence was added as a technical correction to FDAAA in Pub. L. 110-316, 122 Stat. 3509, 3524, section 301, enacted August 14, 2008.

- A brief summary of the specific substantive issues raised in the petition that form the basis of the determination.[3]

At FDA's discretion, the information described above is to be conveyed to the applicant either in a written document or through a meeting with the applicant.[4] The information conveyed as part of the notification is to be considered part of the application and subject to applicable disclosure requirements.[5]

C. FDA's Guidance Regarding 505(q)

As a key area of focus in both FDA's Drug Competition Action Plan and FDA's Biosimilar Action Plan,[6] FDA has been working to deter brand name drug companies from "gaming" the system by taking advantage of certain rules, or exploiting loopholes, to delay competition. To address concerns regarding the use of citizen petitions to delay FDA's action on a generic or other abbreviated application, in September 2019, FDA issued the updated guidance titled *Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act.* This guidance finalized the revised draft guidance issued in October 2018.[7]

The guidance is designed to promote a more efficient approach to 505(q) petitions and allow FDA to focus more reviewer resources on scientific reviews. Among other things, this guidance provides FDA's current thinking on what constitutes a 505(q) petition and describes some of the considerations that FDA expects to take into account in determining whether a petition has been submitted with the primary purpose of delaying the approval of an application. The guidance states that

- If FDA determines that a petition has been submitted with the primary purpose of delaying an application, the Agency may note this determination and its basis for that determination in its petition response;

- If FDA determines that a 505(q) petition has been submitted with the primary purpose of delaying an application, the Agency intends to refer the matter to the Federal Trade Commission

- Finally, the guidance states that FDA will highlight these determinations in its annual reports to Congress.

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[3] Section 505(q)(1)(B) of the FD&C Act.

[4] Section 505(q)(1)(C) of the FD&C Act.

[5] Section 505(q)(1)(D) of the FD&C Act.

[6] See https://www.fda.gov/news-events/fda-brief/fda-brief-fda-issues-final-guidance-address-gaming-use-citizen-petitions. For information regarding the Drug Competition Action Plan, see https://www.fda.gov/drugs/guidance-compliance-regulatory-information/fda-drug-competition-action-plan. Information about the Biosimilar Action Plan is available at https://www.fda.gov/media/114574/download.

[7] See https://www.fda.gov/media/130878/download.

III. Information Reported

Section 505(q)(3) of the FD&C Act requires FDA to submit an annual report to Congress containing statistical information regarding the approval of certain applications and the effect, if any, that 505(q) petitions have had on the timing of such approvals. This annual report complies with the statutory reporting requirements for FY 2021, based on data from October 1, 2020, through September 30, 2021.

Section 914 of FDAAA requires the following information to be included in the report:

- The number of ANDAs, 505(b)(2) applications, and 351(k) applications approved during the reporting period;
- The number of such applications that were delayed by 505(q) petitions;
- The number of days by which the applications were delayed; and
- The number of 505(q) petitions that were submitted during the reporting period.

During the FY 2021 reporting period, the Agency approved 679 ANDAs, 38 505(b)(2) applications, and three 351(k) applications. In this reporting period, no approvals for ANDAs, 505(b)(2) applications, or 351(k) applications were delayed because of a 505(q) petition. During FY 2021, FDA received five 505(q) petitions.

As noted, FDA stated in its final guidance on 505(q) petitions that FDA would highlight in its annual reports to Congress FDA's determinations regarding 505(q) petitions submitted with the primary purpose of delaying the approval of a pending application. During the FY 2021 reporting period, FDA did not conclude that any 505(q) petition was submitted with the primary purpose of delaying the approval of an application.[8]

IV. Petition Review and Observations

In FY 2021, FDA received a total of five petitions subject to section 505(q). In FY 2021, FDA timely responded to all but one of the 505(q) petitions with statutory due dates that fell within that fiscal year.[9]

[8] As stated in footnote 1, FDA received a 505(q) petition on November 8, 2021, which falls within the FY 2022, rather than FY 2021, reporting period, and stated in its December 15, 2021, response that the petition appeared to have been submitted for the primary purpose of delay and that it failed to raise valid scientific or regulatory issues. FDA referred this petition to the Federal Trade Commission. See Docket No. FDA-2021-P-1211.

[9] Depending upon when a citizen petition is submitted, the due date may not fall within the same fiscal year that it is submitted.

FDA continues to monitor the number and nature of 505(q) petitions submitted and continues to analyze whether section 505(q) is effectively discouraging petitioners from submitting petitions primarily to delay the approval of applications. Also, FDA is monitoring the effect of 505(q) petitions and the statutory response period for these petitions on the other work of the Agency. Although FDA has generally met the statutory deadlines for 505(q) petitions, it has done so in part by redirecting efforts that otherwise would have been directed to other work, including responding to other citizen petitions.

Table 1 summarizes the outcomes for the 255 petitions that have been resolved under section 505(q) as of September 30, 2021. The possible outcomes include the following:

- **Denied**: FDA denied the 505(q) petition's requests, including instances when FDA issued a denial without comment on the substance of one or more of the requests.
- **Granted**: FDA granted the 505(q) petition's requests.
- **Denied in Part/Granted in Part**: FDA denied some of the 505(q) petition's requests and granted others, including instances when FDA denied one or more of the requests without comment on the substance of the request.
- **Withdrawn**: The petitioner withdrew the 505(q) petition.

Table 1. Outcomes of 505(q) Petitions Resolved During Fiscal Years 2008-2021.

	FY Resolved	Denied	Granted	Denied/ Granted in Part	Withdrawn	Total # of Resolutions
Fiscal Year	2008	10	1	3	0	14
	2009	16	2	6	0	24
	2010	16	2	6	0	24
	2011	10	1	9	2	22
	2012	10	1	2	0	13
	2013	21	1	5	0	27
	2014	15	0	8	2	25
	2015	16	0	2	0	18
	2016	13	0	1	1	15
	2017	14	2	11	1	28
	2018	19	0	1	1	21
	2019	7	0	1	0	8
	2020	12	0	0	1	13
	2021	2	0	1	0	3
	Total	181	10	56	8	**255**

As of September 30, 2021, 181 petitions (approximately 71 percent) responded to under section 505(q) have been denied, 56 petitions (approximately 22 percent) have been denied in part and granted in part, 10 petitions (approximately 4 percent) have been granted, and 8 petitions (approximately 3 percent) were voluntarily withdrawn by the petitioner.

V. Conclusion

The number of 505(q) petitions decreased in FY 2021 from the prior fiscal year, and the number of 505(q) petitions submitted has trended downward in the past few years. A factor that may have contributed to this decrease is the interpretations of the statute described in the final guidance "*Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act*," issued in September 2019. The guidance describes FDA's current thinking on some of the factors the Agency generally intends to consider in determining whether a petition was submitted with the primary purpose of delay and describes the added scrutiny regarding the purpose, and the scientific validity, of the requests in 505(q) petitions that FDA intends to apply. The approach described in this guidance may have lessened the impact that FDA review of certain citizen petitions may have on any pending approval actions and helped FDA allocate resources efficiently by changing how 505(q) petitions are prioritized. It is unclear whether the decrease will continue. FDA will continue to monitor these trends in light of FDA's previously expressed concern that section 505(q) of the FD&C Act does not discourage the submission of petitions that are intended primarily to delay the approval of competing drug products and do not raise valid scientific issues. However, the trend does appear to be moving toward submission of fewer citizen petitions that fall under section 505(q).

The FD&C Act requires FDA to prioritize 505(q) petitions above other matters, such as petitions raising safety concerns, that may raise important public health concerns. FDA remains concerned about the resources required to respond to 505(q) petitions within the 150-day deadline at the expense of completing the other work of the Agency.[10]

[10] Section 505(q)(1)(F) of the FD&C Act governs the time frame for final Agency action on a petition. Under this provision, FDA shall take final Agency action on a petition not later than 150 days after the date on which the petition is submitted. The 150-day period is not to be extended for any reason, including any determination made under section 505(q)(1)(A) regarding delay of approval of an application, the submission of comments or supplemental information, or the consent of the petitioner.

This report was prepared by FDA's Center for Drug Evaluation and Research.
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