REPORT TO CONGRESS

Twelfth Annual Report on Delays in Approvals of
Applications Related to Citizen Petitions and
Petitions for Stay of Agency Action
for Fiscal Year 2019

Required by Section 914 of the Food and Drug Administration
Amendments Act of 2007

Public Law 110-85

Department of Health and Human Services
Food and Drug Administration

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Commissioner of Food and Drugs

EXECUTIVE SUMMARY

Section 505(q) of the Federal Food, Drug, and Cosmetic Act (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 section 505(b)(2) or 505(j) of the FD&C Act or 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 (PHS 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) 2019 reporting period, FDA approved 935 ANDAs, 52 505(b)(2) applications, and 11 351(k) applications. No approvals for ANDAs, 505(b)(2) applications, or 351(k) applications were delayed because of a 505(q) petition in this reporting period. During FY 2019, FDA received 11 505(q) petitions.

FDA has reviewed the data regarding the outcomes of 505(q) petitions resolved during FY 2008- through FY 2019 (Table 1). Although the number of petitions decreased from the prior year, it is unclear what factor(s) have led to the decrease and whether the decrease will continue. Therefore, FDA continues to be concerned that section 505(q) 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. Further, the statute requires FDA to prioritize these petitions above other matters that raise important public health issues, such as petitions raising safety concerns. Although FDA has generally met the statutory deadlines for 505(q) petitions, it did so in part by redirecting efforts that otherwise would have been directed to other work, including responding to other citizen petitions. In September 2019 (towards the end of the reporting period for this report), FDA published its final guidance on 505(q). As FDA applies its current thinking described in the final guidance, FDA will continue to monitor 505(q) petitions and their effects on generic competition and on the Agency's other work. In addition, as noted in the guidance, FDA will highlight in these annual reports FDA's determinations regarding petitions submitted with the primary purpose of delaying application approval.

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I. STATUTORY REQUIREMENT

The Food and Drug Administration Amendments Act of 2007 (FDAAA) 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 (the 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) 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 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. 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, for example, that the Agency:

- 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.

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

[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.* The Center for Drug Evaluation and Research (CDER) is responsible for responding to petitions submitted under section 505(q).

B. Delays of Approvals

Section 505(q)(1)(A) 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 under section 505(b)(2) or 505(j) of the FD&C Act or 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
- A brief summary of the specific substantive issues raised in the petition which 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]

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[2] This sentence was added as a technical correction to FDAAA in Public Law 110-316, 122 Stat. 3509, 3524, section 301, enacted August 14, 2008.
[3] FD&C Act, section 505(q)(1)(B).
[4] FD&C Act, section 505(q)(1)(C).
[5] FD&C Act, section 505(q)(1)(D).

C. FDA Guidance Regarding 505(q)

As a key area of focus in both FDA's Drug Competition Action Plan and FDA's Biosimilar Action Plan, 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.[6] To address concerns regarding the use of citizen petitions to delay FDA action on a generic or other abbreviated application, in October 2018, FDA issued a revised draft guidance titled, "Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act." FDA issued the final guidance in September 2019.[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 will take into account in determining whether a petition is 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, we may note our determination regarding the primary purpose of delaying an application and our basis for that determination in our petition response. In addition, if we determine that a petition has been submitted with the primary purpose of delaying an application, we intend to refer the matter to the Federal Trade Commission. Finally, the guidance states that we will highlight in our annual report to Congress our determinations regarding petitions submitted with the primary purpose of delaying application approvals.

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 2019, based on data from October 1, 2018, through September 30, 2019.

The statute 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.

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[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, e.g., https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/fda-working-lift-barriers-generic-drug-competition and https://www.fda.gov/news-events/press-announcements/fda-tackles-drug-competition-improve-patient-access. Information about the Biosimilar Action Plan is available at: https://www.fda.gov/media/114574/download.

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

During the FY 2019 reporting period, the Agency approved 935 ANDAs, 52 505(b)(2) applications, and 11 351(k) applications. No approvals for ANDAs, 505(b)(2) applications, or 351(k) applications were delayed because of a 505(q) petition in this reporting period. During FY 2019, FDA received 11 505(q) petitions.

IV. PETITION REVIEW AND OBSERVATIONS

In FY 2019, FDA received a total of 11 petitions subject to section 505(q). In FY 2019, FDA timely responded to all of the 505(q) petitions with statutory due dates that fell within the fiscal year.[8]

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. FDA also is closely 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, it did so in part by redirecting efforts that otherwise would have been directed to other work, including responding to other citizen petitions.

Table 1 below summarizes the outcomes for the 239 petitions that have been resolved under section 505(q) as of September 30, 2019.

Table 1
Outcomes of 505(q) Petitions
Resolved During Fiscal Years 2008-2018

	FY Resolved	Denied	Granted	Denied/ Granted in Part	Withdrawn	Total # of Determinations
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

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

	2019	7	0	1	0	8
	Total	167	10	55	7	**239**

Outcomes:

- **Denied**: FDA denied the petition's requests. This includes instances where FDA issued a denial without comment on the substance of one or more of the requests.
- **Granted**: FDA granted the petition's requests.
- **Denied in Part/Granted in Part**: FDA denied some of the petition's requests and granted others. This includes instances where FDA denied one or more of the requests without comment on the substance of the request.
- **Withdrawn**: The petitioner withdrew the petition.

As of September 30, 2019, 167 of the petitions (approximately 70 percent) responded to under section 505(q) have been denied. Another 55 petitions (approximately 23 percent) have been denied in part and granted in part. Only 10 petitions (approximately 4 percent) have been granted. An additional 7 petitions (approximately 3 percent) were voluntarily withdrawn by the petitioner.

V. CONCLUSIONS

Although the number of petitions decreased in FY 2019 from the prior year, it is unclear what factor(s) have led to the decrease and whether the decrease will continue. Therefore, the Agency continues to be concerned that section 505(q) 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. The FD&C Act requires FDA to prioritize these 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.

In addition, as noted, in September 2019 (towards the end of the reporting period for this report), FDA published its final guidance on 505(q). As FDA applies its current thinking described in the final guidance, FDA will continue to monitor 505(q) petitions and their effects on generic competition and on the Agency's other work. In addition, as noted in the guidance, FDA will highlight in these annual reports FDA's determinations regarding petitions submitted with the primary purpose of delaying application approval.