



REPORT TO CONGRESS

11th Annual Report on Delays in Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action for Fiscal Year 2018

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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EXECUTIVE SUMMARY

Section 914 of the Food and Drug Administration Amendments Act (FDAAA) amended section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding subsection (q), which applies to certain petitions that request that the Food and Drug Administration (FDA or Agency) take any form of action related either 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 these applications that were delayed by 505(q) petitions;
- The number of days by which any such applications were delayed; and
- The number of 505(q) petitions that were submitted during the reporting period.

During the fiscal year (FY) 2018 reporting period, FDA approved 781 ANDAs, 66 505(b)(2) applications, and 5 351(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 2018, FDA received 17 505(q) petitions.

FDA has reviewed the data regarding the outcomes of 505(q) petitions resolved during FY 2008 to FY 2018. Based on its analysis of the data, FDA continues to be concerned that section 505(q) does not discourage the submission of petitions that (1) are primarily intended to delay the approval of competing drug products and (2) do not raise valid scientific issues. However, the FD&C Act requires FDA to prioritize these petitions above other matters, such as safety petitions, 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. FDA remains concerned about the resources required to respond to 505(q) petitions within the statutory deadline at the expense of completing the other work of the Agency.

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I. STATUTORY REQUIREMENT

The Food and Drug Administration Amendments Act (FDAAA) of 2007 (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 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 either under the abbreviated approval pathways described in section 505(b)(2) or section 505(j) of the FD&C Act or under the abbreviated approval 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 FDA treats these petitions.

Under section 505(q)(3) of the FD&C Act, FDA is required to submit an annual report to Congress, in part, about these petitions.

II. BACKGROUND

A. Citizen Petitions and Petitions for Stay of Agency Action

A citizen petition, which is one such petition to which section 505(q) may apply, 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 FDA 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 allow petitioners to submit petitions for a “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 citizen petitions and petitions for stay of

¹ In this report, an application submitted under 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 is responsible for responding to petitions submitted under section 505(q).

Agency action as *petitions* and will refer to petitions subject to section 505(q) of the FD&C Act as *505(q) petitions*.

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—

- (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.*

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 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 under 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:

- A 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, FDA must convey the information described above to the applicant either in a written document or through a meeting with the applicant.⁴ FDA must consider the

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.

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

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

information conveyed in the document or through the meeting to be part of the application and subject to applicable disclosure requirements.⁵

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 fiscal year (FY) 2018, based on data from October 1, 2017, through September 30, 2018.

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 these applications that were delayed by 505(q) petitions;
- The number of days by which any such applications were delayed; and
- The number of 505(q) petitions that were submitted during the reporting period.

During the FY 2018 reporting period, the Agency approved 781 ANDAs, 66 505(b)(2) applications, and five 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 2018, FDA received 17 505(q) petitions.⁶

IV. PETITION REVIEW AND OBSERVATIONS

In FY 2018, FDA received a total of 17 petitions subject to section 505(q). In FY 2018, FDA timely responded to all the 505(q) petitions with statutory due dates that fell within the fiscal year.

FDA continues to monitor the number and nature of 505(q) petitions submitted and continues to analyze whether section 505(q) effectively discourages petitioners from submitting petitions primarily to delay the approval of other applications. FDA also continues to examine 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

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

⁶ In FDA's 10th Annual Report on Delays in Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action for Fiscal Year 2017, we inaccurately reported that during the reporting period of Oct. 1, 2016, through Sept. 30, 2017, the approval of one 505(b)(2) application was delayed for 28 days because of a 505(q) petition. In fact, that application was delayed during FY 2016, and we had already reported that delay in the Ninth Annual Report on Delays in Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action for Fiscal Year 2016. Accordingly, the FY 2017 report should have reflected that no applications were delayed because of a 505(q) petition.

done 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 231 petitions that have been resolved under section 505(q) (as of September 30, 2018) during FYs 2008 to 2018.

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 |
| | Total | 160 | 10 | 54 | 7 | 231 |

Outcomes:

- **Denied**: FDA denied the petition’s requests. This outcome 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 outcome includes instances where FDA denied one or more of the petition’s requests without comment on the substance of the request.
- **Withdrawn**: The petitioner withdrew the petition.

As of September 30, 2018, 160 (approximately 69 percent) of the 505(q) petitions have been denied; 54 505 (q) petitions (approximately 24 percent) have been denied in part and granted in part; ten 505 (q) petitions (approximately 4 percent) have been granted; and seven 505(q) petitions (approximately 3 percent) were voluntarily withdrawn by the petitioner.

V. CONCLUSION

The Agency remains concerned that section 505(q) does not discourage the submission of petitions that (1) are primarily intended to delay the approval of competing drug products and (2) do not raise valid scientific issues. The FD&C Act requires FDA to prioritize these petitions above other matters, such as safety petitions, that may raise important public health concerns. FDA remains concerned about the resources required to respond to 505(q) petitions within the 150-day statutory deadline at the expense of completing the other work of the Agency. Accordingly, as part of the Drug Competition Action Plan, FDA has been reviewing what actions can be taken to address these issues.⁷ For example, 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*, which FDA subsequently finalized in September 2019.⁸ FDA issued this guidance to promote a more efficient approach to 505(q) petitions and to focus more reviewer resources on scientific reviews.

⁷ 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>.

⁸ See FDA's guidance for industry entitled *Citizens Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act* (September 2019), which is available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/citizen-petitions-and-petitions-stay-action-subject-section-505q-federal-food-drug-and-cosmetic-act>.