

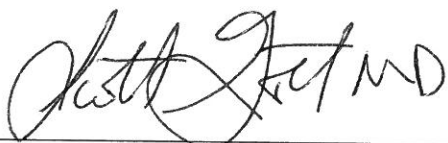
## REPORT TO CONGRESS

Ninth Annual Report on Delays in Approvals of Applications  
Related to Citizen Petitions and  
Petitions for Stay of Agency Action  
for Fiscal Year 2016

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



\_\_\_\_\_  
Scott Gottlieb, M.D.  
Commissioner of Food and Drugs

Date 1-8-18

## EXECUTIVE SUMMARY

Section 505(q) of the Federal Food, Drug, and Cosmetic Act (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 section 505(b)(2) or 505(j) of the FD&C Act or 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 biosimilar biological product 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) 2016 reporting period, FDA approved 651 ANDAs, 51 505(b)(2) applications, and 3 biosimilar biological product applications. No approvals for biosimilar biological product applications or ANDAs were delayed because of a 505(q) petition in this reporting period. The approval of one 505(b)(2) application was delayed because of one 505(q) petition. During FY 2016, FDA received 19 505(q) petitions.

FDA has reviewed the data regarding the outcomes of 505(q) petitions resolved during FY 2008-through FY 2016 (Table 1). Based on its analysis, FDA continues to be concerned that section 505(q) may not be discouraging 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 statute requires FDA to prioritize these petitions above other matters, such as safety petitions, that do raise important public health 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. 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.

**Table of Contents**

I. STATUTORY REQUIREMENT ..... 3

II. BACKGROUND ..... 3

    A. Citizen Petitions and Petitions for Stay of Agency Action..... 3

    B. Delays of Approvals ..... 4

III. INFORMATION REPORTED ..... 5

IV. PETITION REVIEW AND OBSERVATIONS ..... 5

V. CONCLUSIONS ..... 7

## 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 (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 in the biosimilars approval pathway described in section 351(k) of the Public Health Service Act (PHS Act).<sup>1</sup> 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.”

---

<sup>1</sup> 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 *biosimilar biological product 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), together with section 505(q)(5), describes the general scope of section 505(q). 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.<sup>2</sup>

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 biosimilar biological product 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.<sup>3</sup>

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.<sup>4</sup> The information conveyed as part of the notification is to be considered part of the application and subject to applicable disclosure requirements.<sup>5</sup>

---

<sup>2</sup> 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.

<sup>3</sup> FD&C Act, section 505(q)(1)(B).

<sup>4</sup> FD&C Act, section 505(q)(1)(C).

<sup>5</sup> FD&C Act, section 505(q)(1)(D).

### 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 2016, based on data from October 1, 2015, through September 30, 2016.

The statute requires the following information to be included in the report:

- The number of ANDAs, 505(b)(2) applications, and biosimilar biological product 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 2016 reporting period, the Agency approved 651 ANDAs, 51 505(b)(2) applications, and 3 biosimilar biological product applications. The approval of one 505(b)(2) application was delayed because of one 505(q) petition. No approvals for biosimilar biological product applications or ANDAs were delayed because of a 505(q) petition in this reporting period. During FY 2016, FDA received 19 505(q) petitions.

FDA's decision to delay the approval of one 505(b)(2) application during this reporting period was based on the Agency's assessment that further review of the issues raised in the 505(q) petition was required to fully assess the petitioner's arguments against approval. FDA was concerned that if it approved the 505(b)(2) application before resolving the issues raised in the petition and later concluded that one or more of the arguments against approval were meritorious, then the presence on the market of a drug product that did not meet the requirements for approval could negatively affect public health. Thus, FDA delayed approval of the 505(b)(2) application for 28 days to complete an analysis of the issues raised in the petition.

### IV. PETITION REVIEW AND OBSERVATIONS

From FY 2008 through FY 2016, FDA received a total of 194 petitions subject to section 505(q). Over this 9-year period, FDA responded to all but 14 of the 505(q) petitions within the statutory time frame that was applicable during that period.<sup>6</sup>

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

---

<sup>6</sup> The 180-day timeframe applied to petitions submitted on or after September 27, 2007 (the date on which section 505(q) was initially effective), through July 8, 2012. Effective July 9, 2012, the amendments in FDASIA reduced the timeframe to 150 days.

efforts that otherwise would have been directed to other work, including responding to other citizen petitions.

Table 1 below summarizes the outcomes for the 182 petitions that have been resolved under section 505(q) as of September 30, 2016.

Table 1  
Outcomes of 505(q) Petitions  
Resolved During Fiscal Years 2008-2016

	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
	Total	127	8	42	5	<b>182</b>

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, 2016, 127 of the petitions (approximately 70 percent) responded to under section 505(q) have been denied. Another 42 petitions (approximately 23 percent) have been denied in part and granted in part. Only 8 petitions (approximately 4 percent) have been granted. An additional 5 petitions (approximately 3 percent) were voluntarily withdrawn by the petitioner.

## V. CONCLUSIONS

The Agency continues to be concerned that section 505(q) allows the submission of petitions that are intended primarily to delay the approval of competing drug products and do not raise valid scientific issues. The FDA statute requires FDA to prioritize these petitions above other matters, such as safety petitions, that do raise important public health concerns. The Agency 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, when these petitions are not based on public health concerns. Accordingly, as part of the Drug Competition Action Plan, FDA is reviewing what actions can be taken to address these issues.