

REPORT TO CONGRESS

**SECOND ANNUAL REPORT ON DELAYS IN APPROVALS OF
APPLICATIONS RELATED TO CITIZEN PETITIONS AND
PETITIONS FOR STAY OF AGENCY ACTION
FOR FISCAL YEAR 2009**

**REQUIRED BY SECTION 914 OF THE FOOD AND DRUG
ADMINISTRATION AMENDMENTS ACT**

PUBLIC LAW 110-85

**Department of Health and Human Services
Food and Drug Administration**

STATUTORY REQUIREMENT

The Food and Drug Administration Amendments Act (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 Act) (21 U.S.C. 355) by adding new subsection (q). Section 505(q) applies to certain petitions that request that FDA take any form of action related to a pending application submitted under section 505(b)(2) or 505(j) of the Act¹ and governs the manner in which these petitions are treated.

Section 505(q)(3) of the Act states:

- The Secretary shall annually submit to the Congress a report that specifies—
- (A) the number of applications that were approved during the preceding 12-month period;
 - (B) the number of such applications whose effective dates were delayed by petitions referred to in paragraph (1) during such period;
 - (C) the number of days by which such applications were so delayed; and
 - (D) the number of such petitions that were submitted during such period.

I. BACKGROUND

A. Citizen Petitions and Petitions for Stay of Agency Action

Citizen petitions are a vehicle that stakeholders outside of the Food and Drug Administration (FDA or the agency) can use to ask FDA to take (or refrain from taking) an action. For example, a petitioner can ask the agency to:

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

FDA regulations provide the opportunity for any interested person to submit a citizen petition requesting 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 and 10.30). A petition can also be submitted to stay (delay) the effective date of any administrative action, such as the approval of a certain drug application (21 CFR

¹ In this report, an application submitted under section 505(b)(2) of the Act is referred to as a *505(b)(2) application* and an application submitted under section 505(j) of the Act is referred to as an *abbreviated new drug application (ANDA)*.

10.35). Both citizen petitions and petitions for stay of agency action will be collectively referred to as “petitions” throughout this report.

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) 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 Act and the term *petition* is defined as a request described in section 505(q)(1)(A)(i).

If FDA determines, based upon a request for action on a pending application, that a delay of approval of the abbreviated new drug application (ANDA) or 505(b)(2) 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:³

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.

At FDA’s discretion, the information is to be conveyed by either a document or 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

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 Section 505(q)(1)(B).

⁴ Section 505(q)(1)(C).

⁵ Section 505(q)(1)(D).

II. STATUTORY REPORTING REQUIREMENT

As described above, section 505(q)(3) of the Act requires that FDA submit an annual report to Congress containing statistical information regarding the number of ANDAs and 505(b)(2) applications approved and the number of those applications delayed by 505(q) petitions during the reporting period. This second annual report complies with the requirement for fiscal year 2009.

A. Reporting Period

This report is based on fiscal year data from October 1, 2008, through September 30 2009.⁶

B. Information Included in the Report

Section 505(q)(3) of the Act requires that FDA's report to Congress include the following information:

1. **The number of applications that were approved during the preceding 12-month period from October 1, 2008 through September 30, 2009: 489 ANDAs and 35 505(b)(2) applications; and,**
2. **The number of such applications whose effective dates were delayed by petitions referred to in paragraph (1): One ANDA was delayed by a 505(q) petition⁷ from October 1, 2008 through September 30, 2009.**

FDA made the decision to delay the approval of the pending ANDA while it conducted an evaluation of the issues raised in the petition to determine whether a further delay of the approval of the ANDA was necessary to protect the public health under section 505(q)(1)(A)(ii). FDA considered whether the following outcome would be applicable in this case:

If FDA approved the ANDA before the agency completed the substantive review of the issues in the petitions and, after further review, concluded that the petitioner's arguments against approval were meritorious, the presence on the market of drug products that did not meet the requirements for approval could negatively affect the public health.

Once the FDA completed its review of the issues raised by the petition, it determined that further delay of approval of the ANDA was not necessary to

⁶ The first annual report covered the period from the date of enactment (September 27, 2007) through September 30, 2008.

⁷ This report does not provide data on pending applications whose effective dates may have been delayed by petitions that are not subject to section 505(q) of the Act (see section 505(q)(3)(B) referencing petitions referred to in paragraph (1)).

protect the public health, and the agency approved the ANDA prior to issuing a response to the petition.

No 505(b)(2) applications had approval delayed by 505(q) petitions during the reporting period.

3. **The number of days by which such applications were so delayed:** After reviewing the ANDA delayed during the reporting period, FDA determined that the ANDA was delayed by 27 days because of the 505(q) petition; and,
4. **The number of such petitions that were submitted during such period:** The number of 505(q) petitions submitted from October 1, 2008, through September 30, 2009, was 31.

III. CONCLUSION

FDA continues to work to implement the provisions of section 505(q). In January 2009, the agency issued a 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*. This draft guidance addresses the following topics:

Information regarding FDA's current thinking on interpreting section 505(q) regarding how FDA determines (1) if the provisions of section 505(q) addressing the treatment of petitions apply to a particular petition and (2) if a petition would delay approval of a pending ANDA or 505(b)(2) application;

How FDA interprets the provisions of section 505(q) requiring (1) that a petition include a certification and (2) that supplemental information or comments to a petition include a verification; and,

The relationship between the review of petitions and the review of pending ANDAs and 505(b)(2) applications for which FDA has not yet made a decision on approvability.

FDA also is considering issuing regulations through notice-and-comment rulemaking to further implement section 505(q).

Although FDA now has 2 years of experience implementing section 505(q), it believes it may still be too early to make a determination as to whether section 505(q) is effectively discouraging petitions submitted with the primary purpose of delaying approval of an ANDA or 505(b)(2) application. FDA notes, however, that the number of 505(q) petitions submitted during fiscal year 2009 increased by more than 47 percent over the number submitted during the first reporting period. FDA has met the 180-day timeframes for these petitions by redirecting efforts previously directed to other work.

During the period from October 1, 2008 through September 30, 2009, FDA responded to 23 petitions subject to section 505(q) within the 180-day statutory timeframe. FDA

responded to two additional petitions where the statutory timeframe was missed. The number of applications that have been delayed by petitions subject to section 505(q) is extremely low — three ANDAs and no 505(b)(2) applications in 2 years. In a few instances, FDA has responded to 505(q) petitions earlier than required by the statutory timeframe because a related application was ready for approval. In most instances, however, the statutory deadline for responding to a 505(q) petition has occurred before any related ANDAs or 505(b)(2) applications were ready for approval.

FDA continues to monitor closely the petitions submitted under section 505(q) and notes the following areas of concern:

FDA continues to receive 505(q) petitions from ANDA and 505(b)(2) applicants and not solely from innovator companies;

FDA is seeing an increase in petitions for reconsideration pursuant to 21 CFR 10.33, requiring the agency to readdress issues that have already been decided; and

FDA has also received serial 505(q) petitions frequently from the same petitioner about a specific drug product or class of drug products, sometimes resulting in several petition responses about different aspects of the same product.

If these areas of concern become trends, they may undermine the goal of discouraging the submission of petitions that do not raise valid scientific issues and have the effect of improperly delaying approval of ANDAs or 505(b)(2) applications.