

FDA Issues Draft Guidance on Citizen's Petitions

January 29, 2009

On January 21, 2009, the Food and Drug Administration ("FDA") issued a draft guidance titled "Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act," setting forth the FDA's interpretation of the new provision for public comment.

Section 505(q) applies to citizen petitions submitted pursuant to 21 C.F.R. § 10.30 and to petitions for stay of FDA action submitted pursuant to 21 C.F.R. § 10.35 (collectively referred to as "petition(s)"). When these petitions request that the FDA take action relating to a pending 505(b)(2) application or abbreviated new drug application ("ANDA"), Section 505(q) provides that approval of the 505(b)(2) application or ANDA will not be delayed, unless the Secretary determines that a delay is necessary to protect the public health. Additionally, under Section 505(q), the FDA must "take final agency action on a petition not later than 180 days after the date on which the petition is submitted."

The FDA's draft guidance discusses how the FDA will determine if Section 505(q) applies to a specific petition. First, the FDA addresses several procedural requirements.

- The FDA interprets Section 505(q) to apply to petitions that were submitted on or after September 27, 2007.
- The FDA states that the petition must be submitted in writing and pursuant to 21 C.F.R. §10.30 or §10.35 and "may not cross-reference or rely upon information that is not included in the petition."
- The FDA states that there must be a pending 505(b)(2) application or ANDA at the time the petition is submitted.
- The FDA interprets Section 505(q) to apply only to petitions that request the FDA to take action that may delay the FDA's approval of a pending 505(b)(2) application or ANDA.

Additionally, Section 505(q)(4) itself provides two exceptions: it does not apply to petitions "relat[ing] solely to the timing of approval of an application pursuant to ... section (j)(5)(B)(iv)" (the 180-day exclusivity provision) or petitions from the sponsor of the application that "seek only to have [the Secretary] take or refrain from taking any [form of] action with respect to that application."

The FDA then addresses how it will determine whether a petition will delay approval of a 505(b)(2) application or an ANDA. Should a particular petition satisfy all of the procedural requirements outlined above, the FDA will then determine if the petition may be denied pursuant to section 505(q)(1)(E), "which allows denial of a petition that was submitted with the primary purpose of delaying approval of an application and does not on its face raise valid scientific or regulatory issues." The FDA explains that if the petition may not be summarily denied, it plans to apply a "but for" analysis, asking whether the application would be "ready for approval but for the issues raised by the petition." If the application would be ready for approval, the FDA then would next determine if delay is necessary to protect the public health. Should the FDA decide that a delay is necessary, it will, in compliance with the statutory provisions, notify the applicant no later than 30 days after the Agency's decision. The FDA will inform the applicant of additional data or clarifications that should be submitted so that the FDA may review the petition promptly and will provide "a brief summary of the specific substantive issues raised in the petition which form the basis of the determination."

The FDA's draft guidance also details the certification requirements of Section 505(q)(1)(H) and the verification requirements under Section 505(q)(1)(I). Section 505(q)(1)(H) requires that the certification provided by the statute be included in the original petition. If the certification is missing from the original petition, "the petitioner should (1) submit a letter withdrawing the deficient petition pursuant to § 10.30(g) and (2) submit a new petition that contains the certification." The FDA interprets the 180-day time frame for its response to begin at the time that the new petition is submitted. Similarly, the FDA states that if the verification is missing from comments or supplemental information that have been submitted, those, too, should be resubmitted in accordance with the statute.

Finally, the FDA's draft guidance addresses the relationship between review of petitions pursuant to Section 505(q) and review of 505(b)(2) applications and ANDAs. Specifically, the FDA differentiates between the two, stating that "responses to citizen petitions, including petitions subject to section 505(q) constitute final Agency action and are subject to immediate review by the courts" and "carry with them none of the procedural rights for the affected applicants that attach to a decision to deny approval of an application."

Parties interested in commenting on the draft guidance should submit comments to the FDA no later than March 23, 2009.

For Further Information

If you have any questions regarding the draft guidance or would like more information, please contact [Frederick R. Ball](#), [Elese Hanson](#), any of the other [health law lawyers](#) in the [Pharmaceutical & Biotechnology industry group](#) or the attorney in the firm with whom you are regularly in contact.