FDA Issues Final Guidance on "505(q)" Citizen Petitions, including Factors to be considered in Evaluating Potential Anti-Competitive Behavior

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FDA recently issued final guidance for industry on citizen petitions and requests for stays of agency action that may delay the approval of certain drug and biological product applications. Companies planning to submit such petitions should review the recent guidance, *Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act* ("505(q) Guidance").[1] The guidance addresses several items of potential interest to petitioners, such as: (i) FDA's current thinking about when Section 505(q) applies, (ii) the interaction of petition review and the review of pending applications, and (iii) factors considered by the agency in determining whether a petition has been submitted for the primary purpose of delaying approval of an application, a practice known as "gaming" the petition process.[2] We provide a brief summary of the guidance and note the larger context of FDA actions to prevent gaming of agency processes below.

Background and Summary

Section 505(q) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) applies to certain citizen petitions (CPs) and petitions or requests for a stay of agency action ("request for stay") (collectively, "petitions") that ask FDA to take any form of action related to three types of drug and biologic product applications: (i) new drug applications (NDAs) submitted under Section 505(b)(2) of the FD&C Act ("505(b)(2) applications"), (ii) abbreviated NDAs submitted under Section 505(j) of the FD&C Act (ANDAs), and (iii) biological license applications submitted under Section 351(k) of the Public Health Service Act (BLAs). In particular, Section 505(q) applies when the requested action may delay approval of a pending 505(b)(2) application, ANDA, or BLA. Moreover, if Section 505(q) applies to a petition, then the agency is subject to a 150-day statutory timeline for review.[3]

The 505(q) Guidance finalizes draft guidance announced by the agency last year, and supersedes a previous guidance for industry issued in 2014.[4] The 2019 guidance updates the superseded 2014 guidance to reflect regulatory changes (e.g., changes to the rules governing the petition process), describes a change in FDA's current thinking on what constitutes a 505(q) petition, and includes a discussion of considerations the agency may take into account in determining whether a petition was submitted in order to delay the approval of an application.

Among things, the 505(q) Guidance:

- Describes FDA's current thinking about: (i) how to determine if Section 505(q) applies to a particular petition, and (ii) whether a petition would delay approval of a pending 505(b)(2) application, ANDA, or BLA;

1 FDA, Guidance for Industry, *Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act* (84 Fed. Reg. 49308; Sept. 19, 2019); available at https://www.fda.gov/media/130878/download.

2 See Section 505(q) of the FD&C Act (21 U.S.C. § 355(q)).

3 Section 505(q) (1) (F) of the FD&C Act (21 U.S.C. § 355(q) (1) (F)) requires final agency action on a petition within 150 days.

4 The draft guidance was FDA, Draft Guidance for Industry, *Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act* (83 Fed. Reg. 49935; Oct. 3, 2018). The superseded guidance was issued in November 2014 and titled *Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act.*

- Addresses the relationship between the review of petitions and the review of pending applications for which FDA has not yet made a decision on approvability;
- Discusses the requirements that a petition include a 505(q)-specific certification and that supplemental information or comments include a verification; and
- Discusses some of the factors the agency will consider in determining whether a petition has been submitted with the primary purpose of delaying the approval of an application. These include, but are not limited to:
    - Petitions for which it appears, based on the date that relevant information became known to the petitioner (or reasonably should have been known), that the petitioner has taken an unreasonable length of time to submit the petition;
    - Submission of multiple or serial petitions or supplements raising issues that reasonably could have been known at the time of the initial submission;
    - Submission of a petition close in time to a known, first date upon which a covered pending application could be approved (e.g., submission close in time to the expiration of exclusivity or a relevant patent);
    - Petitions with little or no data or information in support of the scientific positions set forth in the petition;
    - Petitions raising the same or substantially similar issues as a prior petition to which FDA has already substantively responded, particularly if close in time;
    - Petitions concerning standards for approval of a drug product for which FDA has provided an opportunity for public input (e.g., product-specific guidance) and the petitioner has not provided comment other than through the petition;
    - Petitions requesting that other applicants be required to meet standards that are more rigorous than those FDA has determined are needed for the relevant reference listed product or the petitioner's version of the product (e.g., asking that an ANDA sponsor be required to adopt restrictions that were voluntarily adopted by an NDA sponsor);
    - Other relevant considerations (e.g., a history of petitions that FDA has determined were submitted with the primary purpose of delay).

Regarding FDA's decision to include discussion of how it considers whether a petition was submitted for purposes of "gaming" the petition process, we note that this final guidance is just the latest in a series of actions FDA has taken to address the role of actual or perceived anti-competitive behavior in increased drug prices.

Other regulators and private actors are also taking action in this area. For example, the U.S. Federal Trade Commission (FTC) has been very active in the pharmaceutical space, a number of states have enacted or are considering related legislation, the U.S. Congress has seen related legislation introduced, and there has been private civil litigation as well.[5]

Overall, this is a developing area of law and regulation and it represents merely one facet of the larger national conversation about the proper balance between innovation and competition in the context of increasing health care prices. We believe it is an area worth the attention of all drug and biologic product sponsors who may be considering submission of a petition to FDA.

5 See, e.g., FTC, Overview of FTC Actions in Pharmaceutical Products and Distribution (June 2019), available at https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview_pharma_june_2019.pdf.

AGG Observations

- Companies should review the new guidance before drafting or submitting any petitions that may delay approval of pending applications for covered products, as such petitions may be covered by Section 505(q).
    - In some cases, the petitioner may know or believe (e.g., from public information or rumor) that an application is pending for a given product. In other cases, the petitioner is not aware of pending applications that could be affected.
    - We note that FDA does not comment on any pending application, even to confirm whether an application has been submitted or not.
    - The guidance includes a number of sections relevant to the preparation of a petition (e.g., required certification and verification statements).
- Companies should consider the factors listed by FDA as being possible indicators of anti-competitive behavior, and should ensure that the petition is being submitted in good faith.
    - FDA does want to learn of and consider legitimate safety and efficacy concerns. However, the agency has indicated its concern with petitions submitted for a primary purpose of delaying approval of competitors' products. Among other things, FDA does not want to waste scarce resources or delay competition based on frivolous or bad faith petitions.
    - FDA may summarily dismiss petitions determined to be anti-competitive, and may refer such matters to the FTC for review.
    - "Coincidental" timing may be an especially clear red flag. In the event that a company is submitting a petition close to the time that a patent or exclusivity expires, it is particularly important to make clear in the petition how there is a legitimate basis for the requested action by FDA, and why the petition is being submitted at that time.

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