



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0008]

Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act.” This draft guidance revises the guidance for industry entitled “Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and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” issued in November 2014. This draft guidance updates the November 2014 guidance to account for recent regulatory changes and describes a change in FDA’s current thinking on what constitutes a 505(q) petition. In addition, FDA is revising this guidance to describe some of the considerations FDA will take into account in determining whether a petition is submitted with the primary purpose of delaying the approval of an application.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2009-D-0008 for “Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Kim Thomas, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6220, Silver Spring, MD 20993-0002, 301-796-3601.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of 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 provides information regarding FDA’s current thinking on implementing section 505(q) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(q)). Section 505(q) of the FD&C Act governs certain citizen petitions and petitions for stay of Agency action that request that FDA take any form of action related to a pending

application submitted under: (1) section 505(b)(2) of the FD&C Act (referred to in this document as a 505(b)(2) application), (2) 505(j) of the FD&C Act (referred to in this document as an abbreviated new drug application or ANDA), or (3) 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 (42 U.S.C. 262(k), referred to in this document as a 351(k) application).

This draft guidance describes how the Agency determines if: (1) the provisions of section 505(q) of the FD&C Act addressing the treatment of citizen petitions and petitions for stay of Agency action (collectively, petitions) apply to a particular petition and (2) a petition would delay approval of a pending ANDA, 505(b)(2) application, or 351(k) application. This draft guidance also describes how FDA implements the provisions of section 505(q) requiring that: (1) a petition include a certification and (2) supplemental information or comments to a petition include a verification. It also addresses the relationship between the review of petitions and pending ANDAs, 505(b)(2) applications, and 351(k) applications for which the Agency has not yet made a decision on approvability.

This draft guidance revises the 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” issued in November 2014. This draft guidance updates the November 2014 guidance to account for recent regulatory changes to add § 10.31 (21 CFR 10.31) to FDA’s regulations and modify 21 CFR 10.30 and 10.35. The revision also describes a change in FDA’s current thinking on what constitutes a 505(q) petition. In addition, FDA is revising this guidance to describe some of the considerations FDA will take into account in determining whether a petition

is submitted with the primary purpose of delaying the approval of an application under section 505(q)(1)(E) of the FD&C Act.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on citizen petitions and petitions for stay of action subject to section 505(q) of the FD&C Act. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520). The collections of information in 21 CFR 10.20, 10.30, and 10.35 have been approved under OMB control number 0910-0191; the collections of information in § 10.31 have been approved under OMB control number 0910-0679; and the collections of information in 21 CFR 314.54, 314.94, and 314.102 have been approved under OMB control number 0910-0001. The certification and verification statements required under § 10.31(c) and (d) are "public disclosure[s] of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public . . ." (5 CFR 1320.3(c)(2)) and therefore not subject to OMB review under the PRA.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either
<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>
or <https://www.regulations.gov>.

Dated: September 28, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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