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

Guidance for Industry

DRAFT GUIDANCE

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For questions regarding this draft document, contact (CDER) Kim Thomas 301-796-3601.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

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Revision 2

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Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. 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. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance provides information regarding FDA's current thinking on interpreting section 505(q) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Section 505(q) of the FD&C Act[2] 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 described in section 505(b)(2) or 505(j) of the FD&C Act[3] or 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 (PHS Act).[4]

This guidance describes FDA's interpretation of section 505(q) regarding how the Agency determines if (1) the provisions of section 505(q) 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 abbreviated new drug application (ANDA), 505(b)(2) application, or 351(k) application. This guidance also describes how FDA interprets 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 guidance revises the guidance for industry *Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act* issued in November

[1] This guidance has been prepared by the Office of Regulatory Policy in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration.

[2] 21 U.S.C. 355(q). For brevity, in this guidance, references to section 505(q) of the FD&C Act are cited as section 505(q).

[3] 21 U.S.C. 355(b)(2) and (j). In this guidance, an application described in section 505(b)(2) of the FD&C Act is referred to as a 505(b)(2) application and an application submitted under section 505(j) of the FD&C Act is referred to as an abbreviated new drug application (ANDA).

[4] 42 U.S.C. 262(k). In this guidance, an application submitted under section 351(k) of the PHS Act is referred to as a 351(k) application.

2014. This revision updates the November 2014 guidance to account for recent regulatory changes to add 21 CFR 10.31[5] to FDA's regulations and modify 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 that 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).

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

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 FD&C Act by adding a new subsection (q).[6]

Section 505(q), as enacted by FDAAA, applied to certain petitions that request that FDA take any form of action related to a pending ANDA or 505(b)(2) application and governs the manner in which these petitions are treated.

The Food and Drug Administration Safety and Innovation Act (FDASIA) was enacted on July 9, 2012.[7] Section 1135 of FDASIA amended section 505(q) of the FD&C Act in two ways. First, it shortened from 180 days to 150 days FDA's deadline for final Agency action on the petitions subject to section 505(q). Second, with the exceptions noted below, it expanded the scope of section 505(q) to include certain petitions related to 351(k) applications.

The provisions of section 505(q) are described in greater detail below.

A. Scope of Section 505(q)

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 this section 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–

[5] On Nov. 8, 2016, FDA issued a final rule amending certain regulations relating to citizen petitions, petitions for stay of action, and the submission of documents to FDA (81 FR 78500).
[6] Pub.L. 110-85, 121 Stat. 823 (as amended by Pub.L. 110-316, 122 Stat. 3509).
[7] Pub.L. 112-144, 126 Stat. 993.

(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.

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

B. Determination of Delay Necessary To Protect the Public Health

If FDA determines that a delay of approval of an ANDA, 505(b)(2) application, or 351(k) 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:

- 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.[8]

At FDA's discretion, the information is to be conveyed by either a document or a meeting with the applicant.[9] The information conveyed as part of the notification is to be considered part of the application and subject to the disclosure requirements applicable to information in such application.[10]

C. Certification and Verification

Under section 505(q)(1)(H), FDA may not consider a petition for review unless the petition is in writing and signed and contains a certification that is specified in that section. In addition, FDA may not accept for review any supplemental information or comments on a petition unless the submission is in writing and signed and contains a specific verification.[11]

D. Final Agency Action

Section 505(q)(1)(F) governs the timeframe for final Agency action on a petition. Under this provision, FDA shall take final Agency action on a petition not later than 150 days after the date on which the petition is submitted. The 150-day period is not to be extended for any reason, including any determination made under section 505(q)(1)(A) regarding delay of approval of an application, the submission of comments or supplemental information, or the consent of the petitioner.

[8] Section 505(q)(1)(B).
[9] Section 505(q)(1)(C).
[10] Section 505(q)(1)(D).
[11] Section 505(q)(1)(I).

Under section 505(q)(1)(E), FDA may deny a petition at any point if the Agency determines that a petition or a supplement to the petition was submitted with the primary purpose of delaying the approval of an application and the petition does not on its face raise valid scientific or regulatory issues.[12] As discussed further in section III.F of this guidance, section 505(q)(1)(E) also provides that FDA may issue guidance to describe the factors that will be used to determine whether a petition is submitted with the primary purpose of delaying the approval of an application.

E. Judicial Review

Section 505(q)(2) governs judicial review of final Agency action. Section 505(q)(2) does not apply to a petition addressing issues concerning a 351(k) application.[13]

Under section 505(q)(2)(A), FDA shall be considered to have taken final Agency action on a petition if FDA makes a final decision within the meaning of 21 CFR 10.45(d) during the 150-day period or the 150-day period expires without FDA having made a final decision. Under section 505(q)(2)(B), if a civil action is filed against the Secretary with respect to any issues raised in the petition before final Agency action, a court shall dismiss the action without prejudice for failure to exhaust administrative remedies. Section 505(q)(2)(C) describes the information to be included in the administrative record.

F. Exceptions and Reporting

Section 505(q)(4) exempts certain categories of petitions from the provisions of section 505(q) — in particular, petitions relating to 180-day generic drug exclusivity under section 505(j)(5)(B)(iv) and petitions from a 505(b)(2), ANDA, or 351(k) applicant regarding FDA actions with respect to that application. Section 505(q)(3) and section 914(b) of FDAAA also provide for certain reporting requirements from FDA to Congress.

III. DISCUSSION

As described in section II of this guidance, the provisions of section 505(q) addressing the treatment of petitions apply only to certain petitions. These provisions include, for example, the requirements that approval of an ANDA, 505(b)(2) application, or 351(k) application not be delayed by a petition absent an Agency determination that a delay is necessary to protect the public health, the provisions requiring final Agency action on the petition within 150 days of submission, and the provisions requiring a certification or a verification.

We describe below how we determine:

- if the provisions of section 505(q) apply to a particular petition

[12] Section 505(q)(1)(E).
[13] Section 505(q)(4)(B).

- if a petition would delay approval of a pending ANDA, 505(b)(2) application, or 351(k) application

We also describe how we interpret:

- section 505(q)(1)(H) requiring that a petition include a certification
- section 505(q)(1)(I) requiring that supplemental information or comments on a petition include a verification
- section 505(q)(1)(E) stating that the Agency may deny a petition or a supplement to a petition that was submitted with the primary purpose of delaying approval of an application and that does not on its face raise valid scientific or regulatory issues

We also describe the relationship between the review of petitions under section 505(q) and the review of ANDAs, 505(b)(2) applications, and 351(k) applications for which the Agency has not yet made a final decision on approvability.

A. How Does FDA Determine if Section 505(q) Applies to a Particular Petition?

We interpret section 505(q) to apply to a petition only if the petition meets all of the following:

- The petition is submitted to FDA on or after September 27, 2007, (if the subject matter of the petition relates to approval of an ANDA or 505(b)(2) application) or on or after July 9, 2012, (if the subject matter of the petition relates to approval of a 351(k) application)
- The petition is submitted in writing and pursuant to 21 CFR 10.30 or 10.35
- An ANDA, 505(b)(2) application, or 351(k) application is pending at the time the petition is submitted to FDA and the application's user fee goal date is on or before the 150-day deadline for final Agency action on the petition
- The petitioner requests an action that could delay approval of a pending ANDA, 505(b)(2) application, or 351(k) application
- The petition does not fall within any of the exceptions described in section 505(q)(4)

We discuss each criterion in greater detail below.

1. Petition Submitted on or After September 27, 2007, or July 9, 2012

Because section 914 of FDAAA became effective on September 27, 2007, we believe that the provisions of section 505(q) only apply to petitions that are submitted on or after September 27, 2007 (if the subject matter of the petition relates to approval of an ANDA or 505(b)(2) application). We do not believe that section 505(q) applies to any petitions that were submitted before September 27, 2007, because section 505(q) does not state that it applies retroactively to petitions submitted before the effective date. Likewise, we do not believe that section 505(q) applies to any petitions whose subject matter relates to the approval of a 351(k) application if those petitions were submitted before July 9, 2012, because section 505(q) does not state that it applies retroactively to those petitions. In addition, either of these interpretations might impose a

statutory-day deadline for final Agency action on a petition after the deadline has already passed.[14]

Even if section 505(q) were interpreted to apply retroactively, FDA would not be able to review any petition submitted before the applicable date because those petitions would not contain the required certification and, as explained in section III.C of this guidance, the statute does not permit a petitioner to cure the deficiency by supplementing a petition to add the certification to the petition.

2. Petition Submitted in Writing and Pursuant to § 10.30 or 10.35

Under section 505(q) of the FD&C Act, a petition must be submitted in writing and pursuant to § 10.30 or 10.35. Section 10.30 of our regulations describes FDA's general requirements for submitting a citizen petition, and § 10.35 describes our requirements for submitting a request for administrative stay of action. If these requirements are not met, we will not consider section 505(q) to apply to the petition.

We note that communications with the Agency regarding any issues with the potential to delay the approval of an ANDA, 505(b)(2) application, or 351(k) application (regardless of whether the communications are considered to be petitions subject to section 505(q)) are appropriately submitted through the petition process pursuant to § 10.30 or 10.35 rather than as correspondence to the new drug application (NDA), ANDA, 505(b)(2) application, 351(k) application, or another process.[15] Similarly, any communications regarding a citizen petition should be filed as comments in the appropriate docket, not to the NDA, ANDA, 505(b)(2) application, or 351(k) application.

We also remind persons that they may not cross-reference or rely upon information that is not included in the petition. Under §§ 10.30(b) and 10.35(b), petitions must be submitted in accordance with 21 CFR 10.20. Section 10.20(c) requires that "[i]nformation referred to or relied upon in a submission is to be included in full and may not be incorporated by reference, unless previously submitted in the same proceeding." In addition, the certification required for petitions subject to section 505(q) (described in section III.C of this guidance) and the certification required for citizen petitions under § 10.30(b) require the petitioner to certify that "this petition includes all information and views upon which the petition relies." A petition therefore is required to include all information referred to or relied upon by the petitioner. In addition, the petition should contain all information, both favorable and unfavorable, regarding the petitioner's claims.

[14] A petition subject to 505(q) that was submitted on or after September 27, 2007, but before July 9, 2012, is subject to the 180-day deadline. A petition subject to section 505(q) that was submitted on or after July 9, 2012, is subject to the 150-day deadline.

[15] As discussed below, interested persons can express their views on issues related to bioequivalence for a drug product by submitting comments in response to a *Federal Register* notice regarding draft product-specific bioequivalence recommendations, instead of by submitting a petition concerning bioequivalence standards for a drug product.

3. ANDA, 505(b)(2) Application, or 351(k) Application Is Pending at the Time the Petition Is Submitted and the Application's User Fee Goal Date Is On or Before the 150-day Deadline for Final Agency Action on the Petition

Section 505(q)(1)(A) describes the scope of section 505(q) (see section II of this guidance). Section 505(q)(1)(A) specifically references pending applications and contemplates the possibility that approval could be delayed by issues raised in a petition. Therefore, we are implementing section 505(q) to apply only to petitions for which, at the time the petition is submitted, at least one ANDA, 505(b)(2) application, or 351(k) application related to the subject matter of the petition is pending[16] and at least one such application's user fee goal date is on or before the 150-day deadline for final Agency action on the petition.[17]

If there is no related ANDA, 505(b)(2) application, or 351(k) application pending at the time that the petition is submitted, then we will not consider the provisions of section 505(q) to apply to the petition. Likewise, if there is a related ANDA, 505(b)(2) application, or 351(k) application pending at the time that the petition is submitted but the applicable user fee goal date is after the 150-day deadline for final Agency action on the petition, then we will not consider the provisions of section 505(q) to apply to the petition.[18] FDA has determined that this way of implementing section 505(q) aligns with the public health mission of the new drug and generic drug review programs and FDA's commitments under the Prescription Drug User Fee Act, the Generic Drug User Fee Amendments, and the Biosimilar User Fee Act. In particular, the Agency believes that implementation of the processes described in this guidance will align the timelines to review and respond to petitions with the timelines for review of the applications themselves, which will provide greater efficiency for both efforts while still ensuring that scientific and regulatory issues raised in a petition are considered prior to ANDA, 505(b)(2) application, or 351(k) application

[16] Although the existence of a pending application generally is not made public by FDA, a potential petitioner may be aware of the existence of a pending ANDA or 505(b)(2) application because of (1) a paragraph IV patent notification, from the applicant to the NDA holder and the patent owner, stating that the application has been submitted and explaining the factual and legal bases for the applicant's opinion that the patent is invalid or not infringed (see section 505(b)(2)(B) and (j)(2)(B) of the FD&C Act); (2) a public announcement by the applicant disclosing the submission of the application; or (3) the tentative approval of an ANDA or 505(b)(2) application made public by FDA or the applicant. In addition, FDA's website identifies drug products for which the Agency has received an ANDA with a paragraph IV certification. A potential petitioner may be aware of the existence of a pending 351(k) application because of (1) patent information exchanged under provisions of section 351(l) of the PHS Act, (2) information made available from patent infringement proceedings between a biologics license application holder and 351(k) applicant, (3) a public announcement by the applicant disclosing the submission of the application, or (4) the tentative approval of a 351(k) application made public by FDA or the applicant.

[17] User fee goal dates reflect commitments made with respect to the Prescription Drug User Fee Act, Pub. L. 102-571 (as amended by Pub. L. 115-52, Tit. I) for 505(b)(2) applications; the Generic Drug User Fee Amendments, Pub. L. 112-144, Tit. III (as amended by Pub. L. 115-52, Tit. III) for ANDAs; and the Biosimilar User Fee Act, Pub. L. 112-144, Tit. IV (as amended by Pub. L. 115-52, Tit. IV) for 351(k) applications.

[18] If we determine that the provisions of section 505(q) do not apply to a particular petition (e.g., if an application is pending but the applicable user fee goal is after the 150-day deadline for final Agency action on the petition), we intend to address the issues raised in the petition in a timely manner so that we are not delayed in taking action on pending applications. See the Generic Drug User Fee Amendments Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018-2022, available at http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM525234.pdf.

approval. This will help ensure Agency experts do not have to consider petitions separately from application review and therefore prematurely.

We also believe our approach is appropriate to ensure the fair and orderly implementation of section 505(q). The evaluation of whether a related ANDA, 505(b)(2) application, or 351(k) application is pending (and thus the evaluation of whether a petition is subject to the provisions of section 505(q)) will be made at the time that the petition is submitted. If we were to take a "rolling" evaluation approach, the status of the petition could change at any time from (1) a petition that is not subject to section 505(q) to one that is subject to section 505(q) should a related ANDA, 505(b)(2) application, or 351(k) application be submitted before we have taken final Agency action on the petition or (2) a petition that is subject to section 505(q) to one that is not subject to section 505(q) if the related ANDA(s), 505(b)(2) application(s), or 351(k) application(s) are subsequently withdrawn or approved and there are no longer any related applications pending. Such a change in the status of the petition would disrupt the orderly application of the provisions of section 505(q) and the Agency's processing of the petition and also could prejudice petitioners and commenters.

4. Petition Requests an Action That Could Delay Approval of a Pending ANDA, 505(b)(2) Application, or 351(k) Application

As noted, section 505(q)(1)(A) contemplates the possibility that approval of a pending ANDA, 505(b)(2) application, or 351(k) application could be delayed by issues raised in the petition. Therefore, we are implementing section 505(q) by applying it only to petitions that request an action that could delay approval of a pending ANDA, 505(b)(2) application, or 351(k) application. If the action requested by the petition does not have the potential to delay approval of the pending application under any reasonable theory, we will not consider the provisions of section 505(q) to apply to the petition.

5. Petition Does Not Fall Within Any of the Exceptions Described in Section 505(q)(4)

Section 505(q)(4) provides that section 505(q) will not apply to any petitions that:

- relate solely to the timing of approval of an application pursuant to the 180-day exclusivity provision at section 505(j)(5)(B)(iv) of the FD&C Act, or
- are from the applicant of the ANDA, 505(b)(2) application, or 351(k) application and seek only to have FDA take or refrain from taking any action with respect to that application.

If either of these exceptions applies, we will not consider the provisions of section 505(q) to apply to the petition.

B. How Does FDA Determine if a Petition Would Delay Approval of an ANDA, 505(b)(2) Application, or 351(k) Application?

Under section 505(q)(1)(A), FDA shall not delay approval of an ANDA, 505(b)(2) application, or 351(k) application because of a petition unless the Agency determines that a delay is

necessary to protect the public health. To implement this provision, first we determine if the provisions of section 505(q) apply to the petition based on the considerations described in section III.A of this guidance. If the provisions apply, we then determine if the petition may be summarily denied as described in 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).[19]

If we do not find that the petition may be summarily denied, we will determine if the petition would be the cause of a delay in an approval of an ANDA, 505(b)(2) application, or 351(k) application by using a *but for* test. In other words, would the ANDA, 505(b)(2) application, or 351(k) application be ready for approval but for the issues raised by the petition?

- If, regardless of the petition, the ANDA, 505(b)(2) application, or 351(k) application would not be ready for approval within the 150-day period for final Agency action on the petition (e.g., because the applicant receives a complete response letter during the 150-day period), then the petition would not delay the approval, and section 505(q)(1)(A) would not be implicated.

- If the ANDA, 505(b)(2) application, or 351(k) application would be ready for approval but for the resolution of the issues raised in the petition within the 150-day period for final Agency action on the petition, then section 505(q)(1)(A) would be implicated, and we would next determine if a delay of approval is necessary to protect the public health.

We determine if a delay of approval is necessary to protect the public health based on our preliminary evaluation of the issues raised in the petition. The Agency considers the following scenario:

> If the application were to be approved before the Agency completed the substantive review of the issues in the petition and, after further review, the Agency concluded that the petitioner's arguments against approval were meritorious, could the presence on the market of drug products that did not meet the requirements for approval identified by the petitioner negatively affect the public health?

If, after undertaking this analysis, we conclude that the public health could be negatively affected under these circumstances, the Agency will conclude that a delay "is necessary to protect the public health" and will delay approval of the pending application until the issues raised in the petition are resolved. Issues that could implicate the public health include, for example, (1) whether a proposed generic drug product is bioequivalent to the reference listed drug or (2) whether an indication can be safely omitted from the labeling because that indication is protected by a patent.

[19] See section III.F of this guidance.

If we determine that a delay of approval of an application is necessary to protect the public health, we will notify the applicant as required by section 505(q)(1)(B) and (C) of the FD&C Act. Under these provisions, we are required to provide the following information to the applicant not later than 30 days after making the determination:

- 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.

We will convey this information to the applicant by either a letter or a meeting with the applicant.[20] As provided in section 505(q)(1)(D), we will consider the information conveyed in the notification to be part of the application and subject to the disclosure requirements applicable to information in such application. We do not intend to notify the petitioner if a determination has been made that a delay in approval of an application is necessary to protect the public health because the provisions of section 505(q) do not require such a notification to the petitioner. We will resolve any public health issues before approving the application. If we, in the course of considering the petition, later determine that a delay of approval is no longer necessary to protect the public health, we will proceed with approving the application.

Regardless of whether we determine that a delay of approval of an application is or is not necessary to protect the public health, we will continue to consider the 150-day period for final Agency action under section 505(q)(1)(F) to apply to the petition.

C. How Does FDA Apply the Certification Requirements in Section 505(q)(1)(H)?

Section 505(q)(1)(H) of the FD&C Act provides that FDA shall not consider a petition for review unless the petition is in writing and signed and contains the following certification:

> I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) I have taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed to me. I further certify that the information upon which I have based the action requested herein first became known to the party on whose behalf this petition is submitted on or about the following date: _____[in the blank space, provide the date on which such information first became known to such party]. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: _____ [in the blank space, provide the names of such persons or organizations]. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.

[20] See section 505(q)(1)(C).

In addition, 21 CFR 10.31 requires certain citizen petitions and petitions for stay of action, including those petitions subject to section 505(q), to contain this certification. Therefore, all petitions that fall within the scope of section 505(q) must be in writing and signed and contain the complete 505(q) certification to be considered for review by FDA.[21] If, based on the considerations described in section II.A of this guidance, section 505(q) applies to the petition, but the petition is not in writing or signed, or does not contain the complete certification, we will not review the petition.

1. Determination of Whether a Certification Is Complete

As part of our determination of whether a petition contains the complete 505(q) certification, we will evaluate whether (1) the language of the certification in the petition exactly mirrors the language provided in section 505(q) and (2) the petitioner provided a date on which the information first became known to the party on whose behalf the petition is submitted.[22] Because section 505(q) sets forth the exact words to be used in the certification, we will consider a certification to be deficient if every word in the petitioner's certification does not match every word of the certification provided in section 505(q). In other words, the petitioner's certification must correspond verbatim to the certification in section 505(q). For example, if, rather than using the phrase "first became known to the party on whose behalf this petition is submitted," the petitioner substitutes the phrase "first became known to me," we will consider the certification to be deficient. We believe this interpretation is mandated by the statutory language because section 505(q) specifies the exact text of the certification.

Section 505(q) also requires that the petitioner provide in the certification the date on or about which the information first became known to the party. Section 505(q) includes a blank space in the certification for that information. We consider a "date" to include a month, day, and year. Therefore, we will consider a certification to be deficient if the petitioner has not provided the month, day, and year on or about which the information first became known to the party on whose behalf the petition is submitted. For example, if the petitioner provides "May 2010" as the date in the certification, we would consider the certification to be deficient. The text of the certification provided in section 505(q) includes a qualification that the petitioner learned of the information "on or about the following date." Therefore, we believe the certification would accommodate instances in which a petitioner may not know the exact date on which it became aware of the information. To the extent that a petitioner believes further explanation of the date is needed, we believe that the blank space in the certification allows for the insertion of additional information. In addition, there may be instances in which different types of information became known to the petitioner over a period of time. In that case, the petitioner should provide each estimated relevant date and identify the information associated with the particular date. We caution that when adding information, the petitioner should ensure that the words of the certification (except for what is provided in the blank space) continue to exactly match the words of the certification as provided by section 505(q).

[21] See section 505(q)(1)(H) and 21 CFR 10.31. Please note that under section 10.31(a)(1), certification is required for every petition that requests any form of action that could, if taken, delay approval of one of the types of applications described therein, regardless of whether that petition is ultimately found to be subject to the statutory deadline in section 505(q)(1)(F).

[22] See also 21 CFR 10.31.

For example, a certification that we would consider to be complete and acceptable could include additional information explaining the petitioner's specified date or dates as follows:

> I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) I have taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed to me. I further certify that the information upon which I have based the action requested herein first became known to the party on whose behalf this petition is submitted on or about the following date: September 21, 1995 (information about bioavailability issues with the innovator drug); November 12, 2009 (publication of a draft bioequivalence guidance for the drug); March 30, 2010 (information that an ANDA had been submitted). If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: Company A. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.

2. What a Petitioner Should Do if a Certification Is Deficient

We also interpret section 505(q)(1)(H) to require that the certification be included in the original petition. Section 505(q)(1)(H) refers to the "petition" as the subject document that must contain the certification. Because sections 505(q)(1)(E) and 505(q)(1)(I) distinguish between petitions and supplements to petitions,[23] the reference to a petition in section 505(q)(1)(H) refers only to the original petition and not to a supplement. Therefore, if a petition is missing the complete certification, we will not permit a petitioner to cure the deficiency by submitting a supplement to add the certification to the petition.

If a petitioner has submitted a petition that is missing the required certification but is otherwise within the scope of section 505(q) and the petitioner would like FDA to review the 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. In this case, the provisions of section 505(q) governing the treatment of petitions will apply only to the new petition that includes the required certification because we cannot review the deficient petition under section 505(q)(1)(H). In particular, we consider the 150-day timeframe for FDA to take final Agency action on the petition to begin from the date of submission of the new, complete petition and not the original, deficient petition.

FDA will not review a petition that is subject to section 505(q) but is missing the required certification. Under 21 CFR 10.31(c), all petitioners raising issues that could delay the approval of a possible ANDA, 505(b)(2) application, or 351(k) application must include the certification in their petitions to ensure FDA consideration. Although we may contact a petitioner to notify him or her of a missing or deficient certification, we note that it is the

[23] Section 505(q)(1)(I) requires that supplemental information include a verification as described in section III.D of this guidance.

responsibility of the petitioner to ensure that its petition complies with the applicable requirements of section 505(q), as well as all other applicable statutory and regulatory requirements.

D. How Does FDA Apply the Verification Requirements in Section 505(q)(1)(I)?

Section 505(q)(1)(I) provides that FDA shall not accept for review any supplemental information or comments on a petition unless the supplemental information or comments are in writing, signed, and contain the following verification:

> I certify that, to my best knowledge and belief: (a) I have not intentionally delayed submission of this document or its contents; and (b) the information upon which I have based the action requested herein first became known to me on or about _____[in the blank space, provide the date on which such information first became known to such party]. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: _____ [in the blank space, provide the names of such persons or organizations]. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.

Section 505(q)(1)(I) applies to any supplemental information or comments that are submitted to a petition that is subject to section 505(q). If any such supplemental information or comments do not include the required verification, FDA will not review the submission.

In addition, 21 CFR 10.31 requires supplemental information or comments to certain citizen petitions and petitions for stay of action, including those petitions subject to section 505(q), to contain this verification. However, as explained in the preamble to the final rule enacting 21 CFR 10.31 (81 FR 78500, Nov. 8, 2016), the language of the verification included in the regulation contains one minor technical correction to the language of the verification set out in the statute. We changed "I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this *petition*" to "I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this *document*" (emphasis added).

We will consider a verification to be deficient if it does not exactly mirror the words of the verification either in section 505(q)(1)(I) of the FD&C Act or 21 CFR 10.31(d). Because the statute specifies the word "petition" and the regulation specifies the word "document," we will accept either "petition" or "document" in the last sentence of the verification.

As with our approach to the certification as explained in section III.C of this guidance, we also will consider a verification to be deficient if the petitioner or commenter does not provide a month, day, and year for the "date" in the verification.

If a petitioner or commenter has submitted supplemental information or comments without the required verification or with an incomplete verification and the petitioner or commenter would like FDA to review the submission, the petitioner or commenter should resubmit the supplemental information or comments with the required verification to FDA.

FDA will not review any supplemental information or comments to petitions that are subject to section 505(q) if the supplemental information or comments are missing the required verification.[24] All of these petitioners or commenters must include the verification in their supplemental information or comments to a petition to ensure FDA consideration. Petitioners and commenters should not rely on FDA reviewers to notify them that their supplements or comments will not be reviewed because of a missing or deficient verification. In some instances, FDA receives numerous supplements and comments in a docket, and it would be administratively burdensome to monitor all the dockets for 505(q) petitions and notify commenters about the statutory requirement. It is the responsibility of petitioners and commenters to ensure that their supplemental information or comments comply with the applicable requirements of section 505(q), as well as all other applicable statutory and regulatory requirements.

E. What Is the Relationship Between the Review of Petitions Under Section 505(q) and the Review of ANDAs, 505(b)(2) Applications, and 351(k) Applications for Which the Agency Has Not Yet Made a Final Decision on Approvability?

A petition may request that FDA take an action related to a specific aspect of a pending ANDA, 505(b)(2) application, or 351(k) application for which the Agency will not have made a final decision regarding approvability by the date that the petition response is due. As described in section II.D of this guidance, section 505(q)(1)(F) requires FDA to take final Agency action on a petition within 150 days of submission. The review of applications that may be affected by the petition is governed by a separate review process, which will not necessarily be completed by the date the petition response is due.[25] If a petition requests that the Agency take an action related to a specific aspect of a pending application, we will consider the review status of the affected application(s) in determining how it would be appropriate for the Agency to respond to the request to take the action requested in the petition within the 150-day timeframe.

The provisions in section 505 of the FD&C Act and FDA's regulations at 21 CFR part 314 establish certain procedures by which the Agency reviews an NDA or ANDA and notifies an applicant if it determines that an application is approved (§ 314.105) or may not be approved (section 505(c) and 505(j); §§ 314.125 and 314.127), or identifies the deficiencies in the application and the steps an applicant may take to respond to the deficiencies (§ 314.110). In addition, the statute and regulations describe a specific process through which an applicant whose application the Agency has found not to meet the requirements for approval may challenge the Agency's determination (section 505(c)(1)(B) and (d), 505(j)(5)(E); § 314.200). Under this process, the Agency must give the applicant notice of an opportunity for a hearing on whether the application is approvable, with a specific timeframe and process should the applicant request such a hearing. These procedures ensure that applicants have an adequate opportunity to challenge a finding by the Agency that a product does not meet the requirements for approval.

[24] See section 505(q)(1)(I) and 21 CFR 10.31(d).

[25] Even though the application will have a user fee goal date that falls on or before the 150 days for FDA to take final Agency action on the related petition, the action on the user fee goal date may be a complete response rather than an approval.

By contrast, responses to petitions, including petitions subject to section 505(q), constitute final Agency action and are subject to immediate review by the courts, subject to the exception stated in section II.E of this guidance. They therefore carry with them none of the procedural rights for the affected applicants that attach to a decision to deny approval of an application. If we were to respond substantively to a petitioner's request regarding the approvability of a certain aspect of a pending application before we have taken a final action on the approvability of the application as a whole, such response could interfere with the statutory and regulatory scheme governing the review of applications and related procedural rights of applicants.[26] There is no evidence that in enacting section 505(q), Congress intended to limit applicants' procedural rights by requiring that the Agency make decisions that constitute final Agency action on the approvability of specific aspects of a pending application (e.g., the acceptability of a proposed trade name, specific claims proposed in a drug product's labeling) on a piecemeal basis outside of the process established under the FD&C Act and regulations.[27]

In light of these considerations, we do not interpret section 505(q) to require a substantive final Agency decision within 150 days on the approvability of a specific aspect of a pending application. In particular, we do not interpret section 505(q) to require such a decision when a final decision on the approvability of the application as a whole has not yet been made and when rendering such a decision could deprive an applicant of procedural rights established by statute and regulations. In such a situation, as described in the preceding sentence we would expect in the ordinary course to deny a petition without comment on the substantive approval issue.

F. What Considerations May Suggest That a Petition Was Submitted for the Primary Purpose of Delaying Approval of an Application?

Section 505(q)(1)(E) provides that FDA may issue guidance to describe the considerations that will be used to determine whether a petition is submitted with the primary purpose of delaying the approval of an application. Although each case is unique, the following are some of the considerations that FDA expects to take into account in determining whether a petition has been submitted with the primary purpose of delaying an application as contemplated by section 505(q)(1)(E) (this list is not intended to be exhaustive and in any given case no single factor may be outcome determinative):

[26] We also note that under applicable statutory and regulatory provisions, we are generally prohibited from disclosing information regarding applications that have not yet been approved. Depending upon the nature and specificity of a petition, these limitations on disclosure also may circumscribe the Agency's ability to respond substantively to issues raised in a petition that affect a pending application.

[27] In the past, we have responded to requests related to general standards for approval (e.g., bioequivalence criteria for generic drug products) that may pertain to one or more pending drug applications, without commenting on the approvability of any particular aspect of a specific pending application. We distinguish our approach of responding to petitions that involve general policies or standards for approval of a drug application from our approach described above, which applies to petitions that involve narrow issues of approvability of a specific aspect or aspects of a pending application or those in which our review of a given application would inform our decisions regarding the sufficiency of the specific data and information needed for approval. We will continue to evaluate each citizen petition on a case-by-case basis with respect to the appropriateness of responding to the petitioner's requests vis-à-vis any pending applications.

- Submission of a petition where it appears, based on the date that relevant information relied upon in the petition became known to the petitioner (or reasonably should have been known to the petitioner), that the petitioner has taken an unreasonable length of time to submit the petition
- Submission of multiple and/or serial petitions raising issues that reasonably could have been known to the petitioner at the time of submission of the earlier petition or petitions
- Submission of a petition close in time to a known, first date upon which an ANDA, 505(b)(2) application, or 351(k) application could be approved (e.g., submission close in time to the expiration of a blocking patent or exclusivity)
- Submission of a petition without any data or information in support of the scientific positions set forth in the petition
- Submission of a petition raising the same or substantially similar issues as a prior petition to which FDA has already substantively responded, particularly where the subsequent submission closely follows in time the earlier response
- Submission of a petition concerning standards for approval of a drug product for which FDA has provided an opportunity for public input (such as when FDA has issued draft or final product-specific guidance applicable to the drug product) and the petitioner has not provided comment other than through the petition.[28]
- Submission of a petition requesting that other applicants must meet standards for testing, data, or labeling for their products that are more onerous or rigorous than the standards applicable to the applicable listed drug and/or petitioner's version of the same product
- Other relevant considerations including the history of the petitioner with the Agency (such as whether the petitioner has a history of submitting petitions that we have determined were submitted with the primary purpose of delay)

If FDA determines that a petition has been submitted with the primary purpose of delaying an application, we will then determine if the petition may be summarily denied as described in section 505(q)(1)(E) (which allows denial of a petition that was submitted with the primary purpose of delay and does not on its face raise valid scientific or regulatory issues). We will determine, on a case-by-case basis, whether a petition that was submitted with the primary purpose of delay also does not on its face raise valid scientific or regulatory issues and therefore may be summarily denied.

We may note our determination regarding the primary purpose of delaying an application and our basis for that determination in our petition response. In addition, if we determine that a petition has been submitted with the primary purpose of delaying an application, we intend to refer the matter to the Federal Trade Commission. Finally, we will highlight our determinations

[28] We note that there are means other than submission of a petition by which interested persons can express their views on issues related to bioequivalence. FDA has been posting draft product-specific bioequivalence recommendations on its website at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075207.htm and announcing in a *Federal Register* notice the availability of these recommendations and the opportunity for the public to consider and comment on the recommendations. We encourage interested persons to submit any comments related to bioequivalence issues in response to a *Federal Register* notice announcing the recommendations.

regarding petitions submitted with the primary purpose of delaying application approvals in our annual report to Congress.[29]

[29] See section 505(q)(3).