

end of the Volcker Rule Proposal comment period.

By the Commission.

Dated: December 23, 2011.

**Kevin M. O'Neill,**

*Deputy Secretary.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 10

[Docket No. FDA-2011-N-0697]

#### Amendments to Regulations on Citizen Petitions, Petitions for Stay of Action, and Submission of Documents to Dockets

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend certain regulations relating to citizen petitions, petitions for stay of action, and the submission of documents to the Agency. In particular, the proposed rule would establish new regulations to implement certain provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act), which concern certain citizen petitions and petitions for stay of action (PSAs) that involve a request for FDA to take any form of action relating to a pending abbreviated new drug application (ANDA) or 505(b)(2) application. We are making these changes to implement provisions of the Food and Drug Administration Amendments Act of 2007 (FDAAA).

**DATES:** Submit either electronic or written comments by April 2, 2012. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by February 2, 2012, (see section “VI. Paperwork Reduction Act of 1995” of this document). See section II.E of this document for the proposed effective date of a final rule based on this proposed rule.

**ADDRESSES:** You may submit comments, identified by Docket No. FDA-2011-N-0697, by any of the following methods; except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) (see the “Paperwork

Reduction Act of 1995” section of this document).

#### Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

#### Written Submissions

Submit written submissions in the following ways:

- *FAX:* (301) 827-6870.
- *Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

*Instructions:* All submissions received must include the Agency name and Docket No. FDA-2011-N-0697 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the “Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

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

#### FOR FURTHER INFORMATION CONTACT:

Nicole Mueller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6312, Silver Spring, MD 20993-0002, (301) 796-3601.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

###### A. Enactment of Section 505(q)

On September 27, 2007, Congress enacted FDAAA (Pub. L. 110-85). Section 914 of title IX of FDAAA added new section 505(q) to the FD&C Act (21 U.S.C. 355(q)). Section 505(q) applies to certain citizen petitions and PSAs (collectively referred to as petitions) that request FDA to take any form of action related to a pending application submitted under section 505(b)(2) or (j) of the FD&C Act (21 U.S.C. 355(b)(2) or (j)). An application submitted under section 505(b)(2) of the FD&C Act is a type of new drug application (NDA) described in that subsection and is referred to in this document as a

“505(b)(2) application.” An application submitted under section 505(j) is an ANDA for a generic drug product.

Section 505(q) governs the manner in which FDA handles certain citizen petitions and PSAs that ask the Agency to take any form of action related to pending 505(b)(2) applications or ANDAs. Over the years, FDA has received numerous petitions asking the Agency not to approve a particular ANDA or 505(b)(2) application (or classes of these applications concerning a particular drug product or active ingredient) unless certain criteria set forth in the petition are met. In many cases, the petitions have raised scientific and/or legal issues relating to the standards for approval of an application. Examples include: Petitions suggesting a particular method for determining the bioequivalence of a proposed generic product to the reference listed drug (RLD) and petitions maintaining that a proposed generic product does not contain the same active ingredient as the RLD. When submitted early, such as when we are making decisions about the bioequivalence requirements for a generic drug product or before we have received the first ANDA or 505(b)(2) application for a drug product, a petition containing material information can assist us in establishing standards for these applications. However, when petitions are submitted late in the review process for challenged applications and do not raise valid scientific and/or legal issues, they may have the effect of improperly delaying the approval of an application. By enacting section 505(q), Congress indicated a desire to ensure that petitions not be used to improperly delay approval of ANDAs and 505(b)(2) applications.

###### B. Provisions of Section 505(q) of the FD&C Act

Section 505(q)(1)(A) of the FD&C Act specifies that FDA must not delay approval of a pending ANDA or 505(b)(2) application because of any request to take any form of action relating to the application, unless the request is in writing and in a citizen petition submitted under § 10.30 (21 CFR 10.30) or a PSA submitted under § 10.35 (21 CFR 10.35), and the Agency determines, upon reviewing the petition, that a delay is necessary to protect the public health.

Section 505(q)(1)(F) of the FD&C Act governs the timeframe for final Agency action on a petition. Under this provision, FDA must take final Agency action on a petition not later than 180 days after the date on which the petition

is submitted. The 180-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 (i.e., that delay is necessary to protect the public health), the submission of comments or supplemental information, or the consent of the petitioner. In addition, FDA may deny a petition at any point if it 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 (section 505(q)(1)(E) of the FD&C Act). 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 (section 505(q)(1)(E) of the FD&C Act).

Section 505(q) of the FD&C Act also includes certification and verification requirements for certain documents. Under section 505(q)(1)(H) of the FD&C Act, 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, we 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 (section 505(q)(1)(I) of the FD&C Act).

## II. Description of the Proposed Rule

FDA is proposing to amend our regulations on general administrative procedures in part 10 (21 CFR part 10) to implement section 505(q) of the FD&C Act. We are proposing to add new § 10.31, which includes the following provisions:

- Proposed § 10.31(a) states that § 10.31 would encompass all citizen petitions and PSAs that request that the Agency take any action that could, if taken, delay approval of an ANDA or 505(b)(2) application (i.e., petitions and PSAs that are or may be subject to section 505(q) of the FD&C Act).

- Proposed § 10.31(b) would clarify the date of submission for petitions submitted under § 10.31.

- Proposed § 10.31(c) and (d) would codify the certification and verification requirements of section 505(q)(1)(H) and (I). Although the certification and verification requirements of section 505(q)(1)(H) and (I) include that the document be signed, we have not proposed a regulation that explicitly states that submissions under § 10.31 or § 10.35 must be signed because current § 10.20 requires that all submissions

made to the Division of Dockets Management be signed.

We are also proposing minor revisions to §§ 10.20 and 10.30 to conform with the addition of proposed § 10.31.

With respect to § 10.35, administrative stay of action, we are proposing a revision to conform with the implementation of section 505(q). We are also proposing to add new § 10.35(i) to clarify that a petitioner for a stay of action may supplement, amend, or withdraw a PSA, similar to the provision for citizen petitions in current § 10.30(g).

In addition to implementing the provisions in section 505(q) of the FD&C Act, we are proposing minor technical changes to revise §§ 10.30(e)(3) and 10.35(e) to allow the Commissioner of Food and Drugs (the Commissioner) to dismiss petitions as moot.

### A. Submission Date for a Citizen Petition Submitted Under Section 505(q) of the FD&C Act

Proposed § 10.31(b) would make clear that for a petition that could be subject to section 505(q) of the FD&C Act and submitted under proposed § 10.31, the date of submission is the date on which the petition is received by the Division of Dockets Management. Proposed § 10.31(b) also states that the petition must be submitted in accordance with §§ 10.20, 10.30, 10.31, and 10.35, the other relevant regulations regarding citizen petitions and PSAs.

#### 1. Current Regulations Regarding Submission Dates

We are proposing § 10.31(b) because under current § 10.20(e), the submission date for documents submitted to the Division of Dockets Management depends on how the document is submitted to FDA. Current § 10.20(e) states that all submissions to the Division of Dockets Management will be considered as submitted on the date they are postmarked or, if delivered in person during regular business hours, on the date on which they are delivered. The date considerations in current § 10.20(e) apply unless a provision in part 10, an applicable **Federal Register** notice, or an order issued by an administrative law judge specifically states that the documents must be received by a specified date. Section 10.20(e) provides as an example § 10.33(g), which states that a petition for reconsideration will be considered submitted on the date received.

Under current § 10.20(e), which applies to all citizen petitions submitted to the Agency, the computation of time to respond to a citizen petition would depend on the type of delivery service

by which a document is sent to the Division of Dockets Management regardless of the date on which it is actually received by the Division of Dockets Management. Therefore, it is possible for two petitions to have different submission dates even if they are received by the Division of Dockets Management on the same day. For example, if Petition A is sent by U.S. mail, postmarked May 1, 2010, and received by the Division of Dockets Management on May 5, 2010, the submission date for Petition A would be considered to be May 1, 2010 (the date of postmark). If Petition B is sent by courier and hand delivered to the Division of Dockets Management on May 5, 2010, the submission date for Petition B would be considered to be May 5, 2010.

Other part 10 regulations also relate to submission dates:

- Under § 10.35(g), a PSA is considered submitted on the day it is received by the Division of Dockets Management. Therefore, under the current regulations, a document's submission date could be different depending on whether the document is a citizen petition or a PSA.

- Under § 10.30(e), FDA is required to respond to a citizen petition within 180 days of receipt of the petition by approving the petition, denying the petition, or providing a tentative response indicating why the Agency has been unable to reach a decision; this 180-day deadline is based on the date of receipt by the Division of Dockets Management.

#### 2. Submission Date for Petitions Submitted Under Proposed § 10.31

We believe that it is important to be clear regarding what date a petition submitted under § 10.31 will be considered to be submitted because section 505(q)(1)(F) of the FD&C Act imposes a strict deadline for FDA to respond to a petition. Under section 505(q)(1)(F) of the FD&C Act, FDA must take final Agency action on a petition subject to section 505(q) no later than 180 days after the date on which the petition is submitted. The 180-day period is not to be extended for any reason, including any determination made under section 505(q)(1)(A) of the FD&C Act regarding delay of approval of an application, the submission of comments or supplemental information, or the consent of the petitioner.

Accordingly, proposed § 10.31(b) would make clear that the date of submission for all petitions subject to § 10.31 and submitted in accordance with §§ 10.20, 10.30, 10.31, and 10.35 is the date on which a petition is received

by the Division of Dockets Management. We are proposing a conforming change to § 10.20 to clarify that the method of calculating submission dates described in § 10.20 does not apply to petitions subject to § 10.31.

### B. Certification and Verification

#### 1. Current Regulation on Certification for Citizen Petitions

Current § 10.30 regulating citizen petitions requires that a citizen petition contain, among other things, a certification stating that the citizen petition includes all information and views on which the citizen petition relies and that it includes data and information known to the petitioner which are unfavorable to the citizen petition. Current regulations do not include a certification or verification requirement for supplements or comments to a citizen petition or comments to a PSA, and the current requirements are different than those contained in section 505(q) of the FD&C Act.

#### 2. Certification and Verification Required by Section 505(q) of the FD&C Act

Section 505(q)(1)(H) of the FD&C Act requires that any petition subject to section 505(q) include a specified certification. Section 505(q)(1)(I) of the FD&C Act requires that any comments or supplemental information submitted to a petition subject to section 505(q) include a specified verification. We propose to add § 10.31(c) and (d) to our regulation to include the statutory requirement for the submission of a certification and/or a verification under section 505(q) and the precise language of the certification and verification.

#### 3. Proposed Certification Requirement

Consistent with the specific language provided in section 505(q) of the FD&C Act, proposed § 10.31(c) provides that FDA will not consider a petition subject to § 10.31 for review unless the petition is in writing 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: \_\_\_\_\_. 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:

\_\_\_\_\_. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition."

Proposed § 10.31(c) would require that all petitions that request that FDA take any form of action that could, if taken, delay approval of an ANDA or 505(b)(2) application (i.e., petitions that are subject to § 10.31) contain the complete certification required by § 10.31(c) to be considered for review by FDA. If the petition does not contain the complete certification, we will not review the petition.

#### 4. Proposed Verification Requirement

Consistent with the specific language in section 505(q) of the FD&C Act, proposed § 10.31(d) provides that FDA will not accept for review any supplemental information or comments on a petition subject to § 10.31 unless the supplemental information or comments are in writing 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

\_\_\_\_\_. 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:

\_\_\_\_\_. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this document."

We are proposing one minor editorial change to the language of the verification set out in the statute. We propose to change "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 are proposing this change because we believe that the statute contained a technical error when referring to a "petition" and that the obvious congressional intent is that this reference be to the "document" in which the verification would be contained (i.e., supplemental

information or comments on a petition rather than a petition itself).

Under proposed § 10.31(d), if any supplemental information or comments that are submitted to a petition subject to § 10.31 do not include the required verification, FDA would not review the submission.

#### 5. Proposed Requirement That the Certification and Verification Use the Exact Language in the Regulation

With the addition of proposed § 10.31(c) and (d), our regulation would include the precise language of the required certification and verification. We have found that petitioners occasionally alter the statutory language of the certification and verification, thereby potentially changing the meaning intended by Congress when it enacted section 505(q) of the FD&C Act. To avoid any alteration of the meaning of the certification and verification, we are proposing to require that petitioners submit the exact statutory language of the certification and verification, with the exception discussed previously in section II.B.4 of this document. Because section 505(q) of the FD&C Act and proposed § 10.31(c) set 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 proposed § 10.31(c). In other words, the petitioner's certification must correspond verbatim to the certification in proposed § 10.31(c). For example, if a certification states "first became known to me" instead of "first became known to the party on whose behalf this petition is submitted," the certification would be deficient. We believe this interpretation is required by the statutory language because section 505(q) of the FD&C Act specifies the exact text of the certification.

As with our proposed approach to the certification, we would consider a verification to be deficient if it does not exactly mirror the words of the verification under proposed § 10.31(d).

#### 6. Date Includes Month, Day, and Year

Section 505(q) of the FD&C Act and proposed § 10.31(c) also require that the petitioner provide in the certification the date on or about which the information first became known to the party. The certification in proposed § 10.31(c) includes a blank space for that information. We interpret the FD&C Act's reference to "date" to mean a month, day, and year. Therefore, we propose to 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 proposed § 10.31(c) 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.

Similarly, under proposed § 10.31(d), we are proposing that if the petitioner or commenter does not provide a month, day, and year in the verification, FDA will consider the verification to be deficient and will not review the submission.

#### 7. Multiple Dates and Types of Information

FDA recognizes that a petition, supplement, or comment could be based on more than one type of information. Proposed § 10.31(c)(2) would require a petitioner to provide in the certification an estimated relevant date for each type of information if different types of information became known over a period of time. The petitioner must identify the information associated with the particular date. To the extent that a petitioner believes that additional clarification is appropriate, the blank space in the certification that proposed § 10.31(c) designates for the date could accommodate additional information that the petitioner believes is appropriate to explain the date that it has identified. This would be done by providing, in each case in which more than one type of information is relied on, the date followed by an identification of the information associated with that date in parentheses. Thus, for example, a petition might include the following in the space for the 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).

When adding additional information, the petitioner should ensure that the words of the certification (except for information added in the blank space provided) continue to exactly match the words of the certification as provided by proposed § 10.31(c).

Similarly, proposed § 10.31(d) would require that the petitioner or commenter include in the verification each type of information and supply the date each type of information became known. The verification in proposed § 10.31(d) includes a blank space that can accommodate this information.

Under proposed § 10.31(c) and (d), it is the responsibility of the person submitting the petition, supplemental information, or comment to identify each type of information upon which it relies and to supply a date with respect to each such type of information. The failure to provide any information relied upon (and the date) in the certification or verification may result in the failure of FDA to consider that information in its analysis of the petition and would, FDA believes, foreclose the petitioner or the person submitting the supplemental information or comment from relying upon such information in judicial review of FDA's final decision.

#### 8. Petitions That Would Be Required To Include the 505(q) Certification

Proposed § 10.31 would apply to all petitions that request an action that could delay the approval of a possible ANDA or 505(b)(2) application (proposed § 10.31(a)); therefore, all such petitions would be required to include the certification proposed in § 10.31(c).

Because section 505(q)(1)(A) of the FD&C Act specifically references pending ANDA or 505(b)(2) applications, we interpret section 505(q) to apply only to petitions for which, at the time the petition is submitted, at least one ANDA or 505(b)(2) application related to the subject matter of the petition is pending. If there is no related ANDA or 505(b)(2) application pending at the time that the petition is submitted, then we will not consider the provisions of section 505(q) of the FD&C Act to apply to the petition. We believe this interpretation of section 505(q) of the FD&C Act is appropriate because if no related ANDA or 505(b)(2) application is pending at the time that a petition is submitted, the references in section 505(q)(1)(A) to a pending application and delay of approval by a petition would be inapplicable. With respect to the actual submission of the certification and/or verification with a petition, we recognize that petitioners may not be aware of the existence of a pending ANDA or 505(b)(2) application and, therefore, may not know whether to submit the appropriate certification and/or verification under section 505(q) of the FD&C Act. Generally, the existence of an ANDA or a 505(b)(2) application would not be public

information.<sup>1</sup> Therefore, FDA has recommended that any petitioner challenging the approvability of an ANDA or a 505(b)(2) application include the statutory certification to avoid a situation in which a petition that is subject to section 505(q) of the FD&C Act is missing the certification and therefore cannot be reviewed by FDA under the statute. We have stated that in situations where a petitioner submits such a petition, we recommend that the petitioner withdraw the original petition and resubmit a petition that includes the required certification under section 505(q) of the FD&C Act.

We have also stated that although we may contact a petitioner to notify him or her of a missing or deficient certification, it is the responsibility of the petitioner to ensure that his or her petition complies with the applicable requirements of section 505(q) of the FD&C Act as well as all other applicable statutory and regulatory requirements. Contacting petitioners who have submitted deficient petitions represents an administrative burden for the Agency. In addition, we are concerned that our contacting such petitioners could notify the petitioner and the public that an ANDA or 505(b)(2) application for a particular drug product is pending.

By including in proposed § 10.31(a) all petitions that challenge the approvability of a possible ANDA or 505(b)(2) application, all such petitions would be required to include the certification in proposed § 10.31(c). Proposed § 10.31(a) would eliminate the need for FDA to contact a petitioner to advise him or her that the petition must include the 505(q) certification or avoid a delay in dealing with the specific issues contained in a petition because the petitioner must withdraw and resubmit the petition. In addition, we propose that any supplement or comments to a petition that is subject to proposed § 10.31 and that includes the certification in § 10.31(c) must include the verification in § 10.31(d).

<sup>1</sup> 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 will not be 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 Web site identifies drug products for which the Agency has received an ANDA with a paragraph IV certification.

### C. Dismiss Petition as Moot

Although the primary purpose of this rule is to implement section 505(q) of the FD&C Act, we are proposing to add language to § 10.30(e) to allow the Commissioner to dismiss a petition as moot. Because we are making changes to § 10.30 to implement section 505(q) of the FD&C Act, we believe it would be useful to make this minor clarifying change to the regulations. This change is technical in nature and would be applicable to citizen petitions in general, including those subject to section 505(q) of the FD&C Act. Current § 10.30(e) could be read to require that the Commissioner respond to a citizen petition by either granting or denying the requests in the citizen petition, even when circumstances have rendered the requests in the petition moot. Current § 10.30(e) does not by its terms contemplate a situation in which a petition can be dismissed as moot.

Because changes in law, facts, or circumstances occurring after a citizen petition is submitted to the Agency can render the requests contained in a petition moot, we propose to allow the Commissioner to dismiss a petition as moot in these situations. An example of a moot petition would be a petition that requests that the Agency remove a particular drug from the market for safety reasons when, at the time of the response, the drug has already been removed from the market. Another example would be where a petitioner requests a change to a regulation that has been rescinded or withdrawn since the petition was submitted. In such circumstances, it would be appropriate for the Commissioner to dismiss the petition as moot rather than to grant or deny the requests in the petition. This proposed change to our regulations is intended to clarify that, in addition to our authority to grant or deny a petition under our current regulations, the Agency can dismiss citizen petitions as moot in certain circumstances.

When a citizen petition is dismissed as moot, FDA would respond to the petitioner in writing just as we would when granting or denying a petition. We believe, however, that the Agency's justification for dismissing a petition as moot could be brief in comparison to a response granting or denying a petition, and thus would require dedication of fewer Agency resources. FDA's response dismissing a citizen petition as moot, similar to a response granting or denying a petition, would constitute final Agency action as to that citizen petition.

### D. Petitions for Stay of Action

We are proposing a conforming change to § 10.35(b) to clarify the applicable regulations for PSAs that are subject to section 505(q) of the FD&C Act. Section 10.35(b) currently states that "a request for stay must be submitted in accordance with § 10.20 and in the following form no later than 30 days after the date of the decision involved." We propose to add language to § 10.35(b) to provide that petitions for stay subject to § 10.31 must include the certification provided in § 10.31(c). This proposed revision would alert petitioners for stays of action that may be subject to section 505(q) of the FD&C Act that they must also submit the certification in § 10.31(c).

Section 505(q)(1)(A) of the FD&C Act states that FDA must not delay approval of a pending ANDA or 505(b)(2) application because of any request to take any form of action relating to the application unless the request is in writing, is a citizen petition submitted under § 10.30 or a PSA submitted under § 10.35, and FDA determines, upon reviewing the petition, that a delay is necessary to protect the public health. Section 10.35(d) provides that filing a PSA, citizen petition, or other type of petition, or taking another type of action as described in § 10.35(d) will not stay or otherwise delay any administrative action by the Commissioner unless: (1) The Commissioner determines that a stay or delay is in the public interest and stays the action, (2) a statute requires that the matter be stayed, or (3) a court orders that the matter be stayed. In other words, the mere filing of any petition, including a petition under section 505(q) of the FD&C Act, would not stay or otherwise delay administrative action by FDA. See *TMJ Implants, Inc. v. United States HHS*, 584 F.3d 1290, 1300 (10th Cir. 2009). A delay of an administrative action could only occur if FDA chose to take action in response to a particular submission. We are not proposing any changes to § 10.35(d) to implement section 505(q)(1)(A) of the FD&C Act because we believe that the provisions of section 505(q)(1)(A) of the FD&C Act regarding the circumstances in which FDA would stay or delay an administrative action (e.g., approval of an ANDA or 505(b)(2)) would be covered by the current language of § 10.35(d).

As explained previously in this document with respect to citizen petitions under § 10.30(e)(3), we are proposing to add a sentence to § 10.35(e) to allow the Commissioner to dismiss a petition for stay of action as moot.

In addition, we are proposing to add § 10.35(i), which would mirror § 10.30(g) governing citizen petitions and allow a petitioner who has submitted a PSA to supplement, amend, or withdraw a PSA without Agency approval and without prejudice, unless the PSA has been referred for a hearing under 21 CFR parts 12, 13, 14, or 15. Proposed § 10.35(i) would apply to all PSAs, not just PSAs subject to section 505(q) of the FD&C Act. We believe that adding this provision to allow PSAs to be amended, withdrawn, or supplemented is permitted under the FD&C Act and is appropriate to allow petitioners submitting PSAs the same procedural rights as petitioners submitting citizen petitions. By amending this regulation, we are clarifying that it is permissible to amend, withdraw, or supplement a PSA because the current regulations are not specific on this point and our current practice allows a PSA to be amended, withdrawn, or supplemented. Furthermore, under section 505(q)(1)(I) of the FD&C Act, the verification statement that applies to citizen petitions and PSAs refers to supplemental information. Therefore, in drafting this provision, Congress assumed it was possible to provide a supplement to a PSA.

### E. Proposed Effective Date

FDA proposes that any final rule that may issue based on this proposal become effective 60 days after its publication in the **Federal Register**. FDA seeks public comment on its proposed 60-day effective date for any final rule that may issue based on this proposed rule.

### III. Legal Authority

This rule, if finalized, would amend §§ 10.20, 10.30, and 10.35 and add new § 10.31 in a manner consistent with the Agency's current understanding and application of these provisions. FDA is implementing certain provisions of FDAAA that govern petitions subject to section 505(q) of the FD&C Act. FDA has authority to issue regulations for the efficient administration of these provisions under section 701(a) of the FD&C Act (21 U.S.C. 371(a)).

### IV. Environmental Impact

FDA has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

## V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is not a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the annualized compliance costs to individual industry members who submit a petition is estimated to be about \$100, the Agency proposes to certify that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect any final rule to result in any 1-year expenditure that would meet or exceed this amount.

### A. Purpose of the Proposed Rule

Section 505(q) of the FD&C Act concerns the manner in which FDA handles certain citizen petitions and PSAs that request that the Agency take some action related to a pending 505(b)(2) application or 505(j) application (ANDA). Congress was concerned that some petitions may improperly delay the approval of an application if they are submitted late in the review process and do not contain valid scientific, legal, or public health issues. The provisions contained in section 505(q) of the FD&C Act are self-implementing, and FDA has operated under these requirements since FDAAA

became law in September 2007. This proposed rule would codify the certification and verification requirements included in section 505(q) of the FD&C Act extend these requirements to all petitions challenging the approvability of possible ANDAs and 505(b)(2) applications, as well as those submitting supplements and comments to these petitions, clarify how FDA determines the date of submissions for citizen petitions and PSAs subject to section 505(q), and clarify that a petitioner for a PSA may supplement, amend, or withdraw a PSA in a manner similar to that provided in the provisions for citizen petitions. In addition, the proposed rule would allow the Commissioner to dismiss a citizen petition or PSA as moot in certain circumstances.

### B. Benefits of the Proposed Rule

Section 505(q) of the FD&C Act was enacted in light of concerns that some citizen petitions were submitted to delay the approval of ANDAs or 505(b)(2) applications. With the enactment of FDAAA, FDA is required to take final action on a 505(q) petition within 180 days of its receipt. Further, the law requires that an expanded certification statement be included with petitions, and a verification statement be included with supplements and comments to petitions. While these requirements do not specifically preclude anyone from submitting a petition that may delay approval of an ANDA or 505(b)(2) application, the requirement that the person submitting the document reveal the date on which he or she became aware of the information contained in the petition is presumably intended to reduce this type of behavior.

The requirements contained in section 505(q) of the FD&C Act have been in effect for 3 years. FDA received 21 505(q) petitions in fiscal year (FY) 2008, 31 505(q) petitions in FY 2009, and 20 505(q) petitions in FY 2010. Over the same period, however, the number of ANDAs and 505(b)(2) applications whose approvals were delayed decreased slightly, from 2 in FY 2008 to 1 in FY 2009 and 1 in FY 2010. The sample size of only 3 years is too small to conclusively determine whether the statute has caused a reduction in the number of petitions that did not include valid scientific or legal issues whose primary purpose was to delay approval of an application. The existence of the statutory requirement that FDA take final action within 180 days of receipt of a 505(q) petition, consequently reducing delays of

approval, may have had this effect by itself.

By codifying the certification and verification statements (with a minor technical change to the verification language), the proposed rule would reinforce the need for exact wording of both the certification and verification statements. Further, the proposed rule makes clear that each of these two statements requires the identification of a month, day, and year in the place of the date, as opposed to just a year or a month and year. In addition, the proposed rule would clarify that each individual type of information requires its own separate date. By providing additional clarity on the statutory requirements, this proposed rule would likely reduce the number of deficient 505(q) petitions. FDA does not have enough information to estimate this reduction in deficient 505(q) petitions, but believes it will result in lower administrative costs for both industry and FDA.

### C. Costs of the Proposed Rule

#### 1. Industry Labor Costs

Companies involved in pharmaceutical research and manufacturing would incur labor costs due to the rule through their administrative review of the final rule and determination of their compliance responsibilities. All companies involved in this would incur some labor costs, regardless of the frequency of their submission of ANDAs or 505(b)(2) applications or citizen petitions to FDA. Census data from 2007 list 763 companies in its pharmaceutical preparation manufacturing category. FDA estimates that each company will expend about 4 hours to review the final rule and determine any changes it needs to make to its internal administrative policies due to this rule. The pharmaceutical and medicine manufacturing category of the North American Industrial Classification System (NAICS) lists the hourly wage for a manager in this category at about \$54. A 35-percent adjustment to this figure for employee benefits results in total hourly compensation costs of about \$73. A one-time 4-hour review for each company would result in compliance costs of almost \$300 per company, and a total of about \$224,000 for the industry. This equates to an annualized cost (over 5 years at a 7-percent discount rate) of about \$55,000 for the entire industry. These estimates may overstate true compliance costs for review of the rule because companies that are unlikely to submit citizen petitions on even an occasional basis

may not expend as much labor as those that submit petitions more often. FDA invites comment on the estimate of 4 hours of labor to review the final rule and make any adjustment to company policies.

Additional labor costs of the rule would be incurred due to the new requirement that all petitioners challenging the approvability of a possible ANDA or 505(b)(2) application for which an application is not currently pending at FDA submit the appropriate certification, as well as the requirement that any supplements or comments to these petitions include the verification. The implementation of the requirements that 505(q) petitions (concerning the approvability of a pending ANDA or 505(b)(2) application) use the new certification language and that supplements and comments to these petitions use the verification language began with the enactment of FDAAA in September 2007 and are not the subject of the proposed rule. FDA has previously estimated that the statute would result in about 28 additional certifications with petitions and 25 additional verifications with supplements or comments to petitions.

FDA received a yearly average of 32 petitions that challenged the approvability of a possible ANDA or 505(b)(2) application since the end of 2007. This number represents a very small increase over the average for the previous 4-year period. Of these 32 petitions, on average only 25 were 505(q) petitions. FDA uses the difference between these two numbers, or about seven petitions per year, as its

estimate of the number of additional petitions that this proposed rule would require to comply with the 505(q) requirements for certification. FDA estimates that the additional time needed to prepare the certification language in the proposed rule at 30 minutes. The majority of this time represents the additional effort of determining the date on which the information or data included in the petition became known to the person submitting the petition. FDA uses the same pharmaceutical and medicine manufacturing category of the NAICS hourly wage for a manager (adjusted for benefits) of \$73 to calculate this cost. At 30 minutes per petition, the marginal cost to prepare the additional certification language for 1 petition is estimated at \$37. For the average of seven additional petitions that would need the additional language, the total cost to industry is estimated at about \$250 annually.

Additional labor costs would also be incurred for the preparation of certifications for supplements and comments to petitions that challenge the approvability of ANDA applications and 505(b)(2) applications for which there is no pending application at the time of the supplement or comment submission. FDA previously estimated that it would receive about 9 verifications for every 10 certifications in the implementation of the 505(q) provision. Using this ratio, FDA estimates that this proposed rule would result in the submission of verifications amounting to 90 percent of the

additional certifications that it received due to this rule. Since FDA estimated that 7 additional certifications would be submitted due to this rule, FDA estimates that 90 percent of this number, or about 6 verifications, would also be submitted as a result of this rule. At 30 minutes per petition and the same adjusted wage rate of \$73/hour, the additional cost per verification is estimated at \$37. The additional labor costs for the 6 verifications would total to about \$220 per year.

The provision of the proposed rule that would allow a petitioner who has submitted a PSA to supplement, amend, or withdraw a PSA without Agency approval would not impose any marginal costs on industry members. These practices reflect FDA's current policy. Similarly, the provision of this proposed rule that clarifies how FDA determines the submission date for documents received by FDA's Division of Docket Management is also not expected to impose any costs on industry members.

The total one-time costs plus annual costs of this proposed rule are estimated at about \$224,000, with annualized costs (one-time costs annualized over 5 years at a 7-percent discount rate plus annual costs) at about \$55,000 for the entire industry (see table 1 of this document). This estimate reflects a one-time \$300 per company review cost for each industry member (annualized over 5 years at a 7-percent discount rate at about \$70), plus an additional \$37 labor cost per certification or verification submitted.

TABLE 1—INDUSTRY COMPLIANCE COSTS

Labor cost factors	One-time costs	Annual costs	Annualized costs <sup>1</sup>
Final Rule Review .....	\$223,600	.....	\$55,000
Certification Preparation .....	.....	\$250	250
Verification Preparation .....	.....	200	200
<b>Total Costs .....</b>	.....	.....	<b>55,450</b>

<sup>1</sup> Annualized costs represent one-time costs amortized over 5 years at a 7-percent discount rate plus annual costs. At a 3-percent discount rate, annualized costs are reduced by about \$5,400.

2. Costs to the Government

The costs to government for oversight of this proposed rule would be low as a review of the language in an additional seven certifications included with petitions and six verifications included with supplements or comments to petitions would only require 15 minutes for each. FDA believes this cost would not be significant, and emphasizes that the FDA personnel reviewing and

responding to citizen petitions spend the vast majority of the time on the substantive issues included in the documents.

D. Small Business Impact

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because of the very low costs that would be incurred by an individual company submitting a petition or

supplement or comment to a petition, FDA believes that the proposed rule would not have a significant economic impact on a substantial number of small manufacturing entities.

The companies that would be affected by this proposed rule are classified in two NAICS categories by the Census Bureau. The affected industries are NAICS 325412—Pharmaceutical Preparation, and NAICS 325414—Biological Products (except diagnostic). The Small Business Administration

(SBA) defines small entities in the pharmaceutical preparation category as those with less than 750 employees and defines small entities in the biological product (except diagnostic) category as those with less than 500 employees. The most recent Census of Manufactures data that offer the level of detail for establishments at or near the employee size limits as defined by SBA is from 2002. In both of these establishment size categories, large majorities of the establishments meet the criteria as small entities. Even taking into account that many of these establishments are parts of multi-establishment corporations, significant numbers of companies would still qualify as small entities. Preliminary Census data from 2007, though less detailed, show that significant numbers of establishments continue to have fewer than 100 employees across all of these categories. While FDA expects that most companies submitting petitions that challenge the approvability of an ANDA or 505(b)(2) application would be larger than the average-sized company in their industry, FDA concludes that a substantial number of companies would still qualify as small entities.

The cost analysis concluded that the annualized compliance cost of the proposed rule for a company that submitted one additional certification as a result of the rule would be just over \$100. Because FDA estimates that only about seven additional certifications will be submitted due to this rule, it is doubtful that many firms will submit more than one additional certification or verification annually to those already required by section 505(q) of the FD&C Act. Using 2002 Census data, the average value of shipments for establishments in these industries with 1 to 4 employees ranged from \$478,000 to \$824,000 according to the Census of Manufactures. Assuming that such small operations had to prepare even one additional certification or verification each year, the costs of the proposed rule would represent, at most, 0.02 percent of the annual value of shipments. For establishments with 10 or more employees, the compliance costs would represent 0.01 percent or less of the value of shipments. As stated previously, FDA concludes that this proposed rule would not have a significant economic impact on a substantial number of small entities.

## VI. Paperwork Reduction Act

This proposed rule contains collections of information that are subject to review by OMB under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520).

“Collection of information” includes any request or requirement that persons obtain, maintain, retain, or report information to the Agency, or disclose information to a third party or to the public (44 U.S.C. 3502(3) and 5 CFR 1320.3(c)). The title, description, and respondent description of the information collection are shown under this section with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

FDA invites comments on these topics: (1) Whether the collection of information is necessary for proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

*Title:* Amendments to Regulations on Citizen Petitions, Petitions for Stay of Action, and Submission of Documents to Dockets.

*Description of Respondents:* Respondents to this collection of information as it is related to citizen petitions are individuals or households, State or local governments, not-for-profit institutions, and businesses or other for-profit institutions or groups. Respondents to this collection of information as it is related to PSAs are persons who choose to file a petition for an administrative stay of action.

*Description:* FDA is requesting public comment on estimates of annual submissions from these respondents, as required by section 505(q) of the FD&C Act and described in this proposed rule under § 10.31(c) and (d). Section 10.31(c) of this proposed rule requires that citizen petitions and PSAs that are subject to section 505(q) include a certification to be considered for review by FDA. Section 10.31(d) requires that supplemental information or comments to such citizen petitions and PSAs include a verification to be accepted for review by FDA. This proposed rule sets forth the statutory language under section 505(q) requiring the submission of a certification and/or a verification and the precise language of the certification and verification. One of the

criteria for a citizen petition or PSA to be subject to section 505(q) is that a related ANDA or 505(b)(2) application is pending at the time the citizen petition or petition for stay is submitted.

Because petitioners or commenters may not be aware of the existence of a pending ANDA or 505(b)(2) application, this proposed rule requires that all petitioners challenging the approvability of a possible ANDA or 505(b)(2) application include the certification required in § 10.31(c) of this proposed rule and that petitioners and commenters submitting supplements or comments, respectively, to a citizen petition or PSA challenging the approvability of a possible ANDA or 505(b)(2) application include the verification required in section § 10.31(d) of this proposed rule.

FDA currently has OMB approval for the collection of information entitled “General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions” (OMB control number 0910–0183). This collection of information includes, among other things: (1) The format and procedures by which an interested person may submit to FDA, in accordance with § 10.20, a citizen petition requesting the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action (§ 10.30(b)); (2) the submission of written comments on a filed citizen petition (§ 10.30(d)); (3) the submission of a supplement or amendment to or a letter to withdraw a filed citizen petition (§ 10.30(g)); (4) the format and procedures by which an interested person may request, in accordance with § 10.20, the Commissioner to stay the effective date of any administrative action (§ 10.35(b)); and (5) the submission of written comments on a filed petition for administrative stay of action (§ 10.35(c)). This information collection includes citizen petitions, PSAs, comments to petitions, supplements to citizen petitions, and letters to withdraw a citizen petition, as described previously, that are subject to section 505(q) of the FD&C Act and described in this proposed regulation.

OMB recently approved (OMB control number 0910–0679) the information collection in 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” (see the information collection analysis at 75 FR 78249 (December 15, 2010), and the document announcing the availability of the guidance at 76 FR 33309 (June 8, 2011)).

The guidance describes FDA’s interpretation of section 505(q) of the FD&C Act regarding how the Agency will determine 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 ANDA or a 505(b)(2) application. The guidance also describes how FDA will interpret 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.

Finally, the guidance addresses the relationship between the review of petitions and pending ANDAs and 505(b)(2) applications for which the Agency has not yet made a decision on approvability.

Thus, FDA has OMB approval under the PRA for the information collection required under section 505(q) of the FD&C Act and described in the guidance. This information collection is also described in proposed § 10.31(c) and (d).

There is, however, one proposed provision that would require the collection of information that is not

already approved by OMB. Under proposed § 10.35(i), a petitioner may, under certain conditions, supplement, amend, or withdraw a PSA in writing without Agency approval and without prejudice to resubmission at any time until the Commissioner rules on the petition. This proposed provision is explained in section II of this document. FDA estimates that it will receive approximately one supplement, amendment, or withdrawal under proposed § 10.35(i) from approximately one applicant, and that it will take approximately 0.5 hour to make this submission.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Proposed § 10.35(i) .....	1	1	1	0.5	0.5
Total Hours .....	.....	.....	.....	.....	0.5

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The information collection provisions of this proposed rule have been submitted to OMB for review. Interested persons are requested to fax comments regarding information collection by (see **DATES** section of this document) to the Office of Information and Regulatory Affairs, OMB. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: (202) 395-7285, or emailed to *oira\_submission@omb.eop.gov*. All comments should reference the title of this proposed rule and include the FDA docket number found in brackets in the heading of this document.

**VII. Federalism**

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

**VIII. Request for Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**List of Subjects in 21 CFR Part 10**

Administrative practice and procedure, News media.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 10 be amended as follows:

**PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES**

1. The authority citation for 21 CFR part 10 continues to read as follows:

**Authority:** 5 U.S.C. 551–558, 701–706; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

2. Section 10.20 is amended by revising paragraph (e) to read as follows:

**§ 10.20 Submission of documents to Division of Dockets Management; computation of time; availability for public disclosure.**

\* \* \* \* \*

(e) Except as provided in § 10.31(b), all submissions to the Division of Dockets Management will be considered as submitted on the date they are postmarked or, if delivered in person during regular business hours, on the date on which they are delivered, unless a provision in this part, an applicable **Federal Register** notice, or an order issued by an administrative law judge specifically states that the documents must be received by a specified date, e.g., § 10.33(g) relating to a petition for reconsideration, in which case they will be submitted on the date received.

\* \* \* \* \*

3. Section 10.30 is amended as follows:

a. Revise paragraph (b) introductory text;

b. Revise the first sentence of paragraph (c);

c. Revise the second sentence of paragraph (d);

d. Remove from paragraph (e)(2)(ii) the word “or”;

e. Redesignate paragraph (e)(2)(iii) as paragraph (e)(2)(iv);

f. Add new paragraph (e)(2)(iii); and

g. Add to paragraph (e)(3) a new sentence after the first sentence.

The additions and revisions read as follows:

**§ 10.30 Citizen petition.**

\* \* \* \* \*

(b) A petition (including any attachments) must be submitted in accordance with § 10.20 and, if applicable, § 10.31. The certification requirement in this section does not apply to petitions subject to the

certification requirement of § 10.31. The petition must be in the following form:

\* \* \* \* \*

(c) A petition that appears to meet the requirements of paragraph (b) of this section, § 10.20, and, if applicable, § 10.31, will be filed by the Division of Dockets Management, stamped with the date of filing, and assigned a docket number. \* \* \*

(d) \* \* \* The comments are to specify the docket number of the petition, include, if applicable, the verification under § 10.31, and may support or oppose the petition in whole or in part. \* \* \*

(e) \* \* \*

(2) \* \* \*

(iii) Dismiss the petition as moot if at any time the Commissioner determines that changes in law, facts, or circumstances since the date on which the petition was submitted have rendered the petition moot; or

\* \* \* \* \*

(3) \* \* \* If, at any time, the Commissioner determines that changes in law, facts, or circumstances since the date on which the petition was submitted have rendered the petition moot, the Commissioner may dismiss the petition as moot. \* \* \*

\* \* \* \* \*

4. Section 10.31 is added to read as follows:

**§ 10.31 Citizen petitions and petitions for stay of action related to an abbreviated new drug application or a new drug application.**

(a) *Applicability.* This section applies to a citizen petition or petition for stay of action that meets all of the following criteria:

(1) The petition requests that the Commissioner take any form of action that could, if taken, delay approval of an abbreviated new drug application (ANDA) submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) or a new drug application submitted under section 505(b)(2) (a 505(b)(2) application).

(2) The petition is submitted on or after September 27, 2007.

(3) The petition is submitted in writing and under § 10.30 (for citizen petitions) or § 10.35 (for petitions for stay of action).

(b) *Date of submission.* A petition subject to this section and submitted in accordance with §§ 10.20, 10.30, 10.31, and 10.35 is regarded as submitted on the date on which the petition is received by the Division of Dockets Management.

(c) *Certification.* (1) FDA will not consider for review a petition that is subject to this section unless the

petition is in writing and contains the following certification: "I certify that, to my best knowledge and belief: (i) This petition includes all information and views upon which the petition relies; (ii) this petition includes representative data and/or information known to the petitioner that are unfavorable to the petition; and (iii) I have taken reasonable steps to ensure that any representative data and/or information that 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 the person submitting the petition]. 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."

(2) The certification in paragraph (c)(1) of this section must contain one or more specific dates (month, day, and year) in the blank space provided. If different categories of information became known at different times, the certification must contain each estimated relevant date. The information associated with a particular date must be identified.

(d) *Verification.* (1) FDA will not accept for review any supplemental information or comments on a petition that is subject to this section unless the supplemental information or comments are in writing and contain the following verification: "I certify that, to my best knowledge and belief: (i) I have not intentionally delayed submission of this document or its contents; and (ii) 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 the person submitting the document]. 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 document."

(2) The verification in paragraph (d)(1) of this section must contain one or more specific dates (month, day, and year) in the blank space provided. If different categories of information became known at different times, the certification must contain each estimated relevant date. The information associated with a particular date must be identified.

5. Section 10.35 is amended by revising the third sentence of paragraph (b); by adding to paragraph (e) a new sentence after the second sentence; and by adding paragraph (i) to read as follows:

**§ 10.35 Administrative stay of action.**

\* \* \* \* \*

(b) \* \* \* A request for stay must be submitted in accordance with § 10.20 and in the following form (except that stays subject to § 10.31 must include the certification provided in § 10.31(c)) no later than 30 days after the date of the decision involved. \* \* \*

\* \* \* \* \*

(e) \* \* \* If, at any time, the Commissioner determines that changes in law, facts, or circumstances since the date on which the petition was submitted have rendered the petition moot, the Commissioner may dismiss the petition as moot. \* \* \*

\* \* \* \* \*

(i) A petitioner may supplement, amend, or withdraw a petition for stay of action in writing without Agency approval and without prejudice to resubmission at any time until the Commissioner rules on the petition, provided the resubmission is made in accordance with paragraph (b) of this section, unless the petition for stay of action has been referred for a hearing under parts 12, 13, 14, or 15 of this chapter. After a ruling or referral, a petition for stay of action may be supplemented, amended, or withdrawn only with the approval of the Commissioner. The Commissioner may approve withdrawal, with or without prejudice against resubmission of the petition for stay of action.

Dated: December 27, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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