



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 10

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

RIN 0910-AG26

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is amending certain regulations relating to citizen petitions, petitions for stay of action (PSAs), and the submission of documents to the Agency. In particular, the final rule establishes new regulations to implement certain provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), which concern certain citizen petitions and PSAs that involve a request for FDA to take any form of action relating to a pending abbreviated new drug application (ANDA), 505(b)(2) application, or certain applications submitted under the Public Health Service Act (PHS Act). We are making these changes to implement provisions of the Food and Drug Administration Amendments Act of 2007 (FDAAA) and the Food and Drug Administration Safety and Innovation Act (FDASIA).

DATES: This rule is effective [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number (FDA-2011-N-0697) 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: Darren Eicken, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6206, Silver Spring, MD, 20993-0002, 240-402-0978.

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Executive Summary

Purpose of the Rule

This rule establishes new regulations implementing section 505(q) of the FD&C Act (21 U.S.C. 355(q)) as enacted by FDAAA (Pub. L. 110-85) and amended by FDASIA (Pub. L. 112-144). Section 505(q) of the FD&C Act governs the manner in which FDA handles certain citizen petitions and PSAs that ask the Agency to take any form of action related to an ANDA, a 505(b)(2) application, or an application submitted under section 351(k) of the PHS Act (351(k) application) (42 U.S.C 262(k)). Section 505(q) of the FD&C Act specifies that FDA must not delay approval of a pending 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 or a PSA, and the Agency determines, upon reviewing the petition, that a delay is necessary to protect the public health. Section 505(q) of the FD&C Act also requires that all submitters of a petition (or PSA) include with their submission a verbatim certification statement specifying the date on which the information relied on in the petition first became known. Similarly, section 505(q) of the FD&C Act requires that the submitters of a supplement or a comment to a petition include with their submission a verbatim verification statement specifying the date on which the information relied on in their submission first became known. By enacting section 505(q) of the FD&C Act, Congress indicated a desire to ensure that petitions not be used to improperly delay approval of ANDAs, 505(b)(2) applications, or 351(k) applications. This rule clarifies the requirements of section 505(q) of the FD&C Act.

Summary of the Major Provisions of the Rule

This rule amends FDA's regulations on general administrative procedures in part 10 (21 CFR part 10).

In § 10.31, paragraph (a) states that § 10.31 applies to all citizen petitions and PSAs that request that the Agency take any action that could, if taken, delay approval of an ANDA, a 505(b)(2) application, or a 351(k) application (i.e., petitions and PSAs that are or may be subject to section 505(q) of the FD&C Act). Section 10.31(b) clarifies that the date of submission for petitions submitted under § 10.31 is the date on which the petition is received by FDA's Division of Dockets Management.

The rule also codifies the certification and verification requirements of section 505(q) of the FD&C Act. Section 10.31(c) clarifies that the Agency will consider a certification deficient if every word in the petitioner's certification does not match every word of the certification provided in section 505(q)(1)(H) of the FD&C Act. Likewise, § 10.31(d) clarifies that the Agency will consider the verification deficient if every word in the petitioner's or commenter's verification does not match every word of the verification provided in section 505(q)(1)(I) of the FD&C Act. However, because we believe section 505(q)(1)(I) of the FD&C Act contains a technical error when it specifies the word "petition" in the last sentence of the verification, we will accept either the word "petition" or "document" in the last sentence of the petitioner's or commenter's verification.

The rule also amends §§ 10.30 and 10.35. Section 10.30(e)(5) states that FDA intends to respond to a petition subject to section 505(q) of the FD&C Act within 150 days after the date on which the petition is received. This amendment incorporates a statutory change enacted by FDASIA. In addition, § 10.35(i) clarifies that a petitioner requesting a stay of action may

supplement, amend, or withdraw a PSA, similar to the provision for citizen petitions in current § 10.30(g). Finally, §§ 10.30(e)(3) and 10.35(e) are amended to reflect that the Commissioner of Food and Drugs (the Commissioner) may dismiss a petition if changes in law, facts, or circumstances since the date on which the petition was submitted render the petition moot.

Costs and Benefits

We estimate one-time costs to industry from this rule at about \$613,800. We estimate annual costs at about \$1,700. These costs equate to an estimated total annualized cost of about \$89,100 at a 7 percent discount rate over 10 years and about \$73,700 at a 3 percent discount rate over 10 years. The total annualized costs include the administrative cost to review the rule (\$87,400) plus the cost for the additional effort preparing certifications for petitions and verifications for both responses to petitions and supplements to petitions (\$1,700).

By providing additional clarity on the statutory requirements, we expect the rule will slightly reduce the number of deficient 505(q) petitions, leading to lower administrative costs for both industry and FDA.

I. Background

In the Federal Register of January 3, 2012 (77 FR 25), FDA issued a proposed rule to amend certain regulations relating to citizen petitions, PSAs, and the submission of documents to the Agency, to implement provisions of section 505(q) of the FD&C Act. Section 505(q) of the FD&C Act governs certain citizen petitions and PSAs (collectively referred to as petitions) that ask FDA to take any form of action that could, if taken, delay approval of a pending application submitted under section 505(b)(2) or (j) of the FD&C Act or a pending application for licensure of a biological product as a biosimilar or interchangeable product that is submitted under section 351(k) of the PHS Act. 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) of the FD&C Act is an ANDA seeking approval for a generic drug product. An application submitted under section 351(k) of the PHS Act is referred to in this document as a “351(k) application.”

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 demonstrating 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, 505(b)(2) application, or 351(k) application for a drug or biological product, a petition may contain information that can contribute towards our evaluation of an application. 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) of the FD&C Act, Congress indicated a desire to ensure that petitions not be used to improperly delay approval of ANDAs, 505(b)(2) applications, or 351(k) applications.

Scope of section 505(q) of the FD&C Act: FDAAA was enacted on September 27, 2007. Section 914 of Title IX of FDAAA added section 505(q) to the FD&C Act. Section 505(q) of the FD&C Act was subsequently amended by FDASIA on July 9, 2012.

Section 505(q)(1)(A) of the FD&C Act specifies that FDA must not delay approval of a pending ANDA, a 505(b)(2) application, or a 351(k) 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 or a PSA submitted under § 10.35, and the Agency determines, upon reviewing the petition, that a delay is necessary to protect the public health. In section 505(q)(5) of the FD&C Act 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 defined in section 505(q)(1)(A)(i).

Section 505(q)(1)(B) of the FD&C Act states in this context that if FDA determines that a delay of approval of an ANDA, a 505(b)(2) application, or a 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 (1) notification that the determination has been made; (2) 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 (3) a brief summary of the specific substantive issues raised in the petition that form the basis of FDA's determination. At FDA's discretion, the information is to be conveyed either in writing or in a meeting with the applicant. The information conveyed in the notification is to be considered part of the application and is subject to the disclosure requirements applicable to information in the application.

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 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) of the FD&C Act 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).

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 is signed and contains a certification that is specified in that section. Section 505(q)(1)(H) of the FD&C Act sets forth the exact words to be used in the certification. In addition, FDA may not accept for review any supplemental information or comments on a petition unless the submission is in writing and is signed and contains a specific verification. Section 505(q)(1)(I) of the FD&C Act sets forth the exact words to be used in the verification.

Section 505(q)(2) of the FD&C Act governs judicial review of final Agency action on a petition subject to section 505(q). Under section 505(q)(2)(A) of the FD&C Act, FDA will be considered to have taken final Agency action on a petition if FDA makes a final decision within the meaning of § 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) of the FD&C Act, 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) of the FD&C Act, however, does not apply to a petition containing requests relating to a 351(k) application.

II. Overview of the Final Rule, Including Significant Changes to the Proposed Rule

A. Overview

In this rulemaking, the Agency finalizes the provisions outlined in the January 2012 proposed rule. In addition, the final rule incorporates changes enacted by FDASIA and responds to comments made to the proposed rule. FDA also is making editorial and organizational changes to clarify provisions. The final rule amends part 10 of FDA regulations on general administrative procedures. The amendment adds § 10.31, which includes the following provisions:

- Section 10.31(a) states that § 10.31 will encompass all citizen petitions and PSAs that request that the Agency take any action that could, if taken, delay approval of an ANDA, a 505(b)(2) application, or a 351(k) application (i.e., petitions and PSAs that are or may be subject to section 505(q) of the FD&C Act).
- Section 10.31(b) clarifies the date of submission for petitions submitted under § 10.31.
- Section 10.31(c) and (d) codify the certification and verification requirements of section 505(q)(1)(H) and (I) of the FD&C Act. Section 10.31(c) clarifies that the Agency will consider a certification deficient if every word in the petitioner's certification does not match every word of the certification provided in section 505(q)(1)(H) of the FD&C Act. Likewise, § 10.31(d) clarifies that the Agency will consider the verification deficient if every word in the petitioner's or commenter's verification does not match every word of the verification provided in section 505(q)(1)(I) of the FD&C Act. As discussed in section II.B.4 of the preamble to the proposed rule, we are making one minor editorial change to the language of the verification set out in the statute. We are changing "I verify under penalty of perjury that the foregoing is true and correct as of the date of this

petition” to “I verify under penalty of perjury that the foregoing is true and correct as of the date of this document” (emphasis added). Because the statute specifies the word “petition”, we will accept either “petition” or “document” in the last sentence of the verification. In addition, section 505(q) of the FD&C Act requires both the certification and verification to be signed and executed under penalty of perjury. FDA interprets the signature provision to require a handwritten or electronic signature by the person whose name appears as the signatory to the petition, supplement, or comment. If the certification or verification is signed by another person with the notation “for,” signature/[initials], “on behalf of,” or with similar notation that indicates one person signed for another, we will consider the certification or verification to be deficient and will not consider the petition for review.

The final rule amends §§ 10.20, 10.30, and 10.35 as follows:

- Adds § 10.30(e)(5) to incorporate a statutory change enacted by FDASIA. New § 10.30(e)(5) states that FDA intends to respond to a petition subject to section 505(q) of the FD&C Act within 150 days after the date on which the petition is received.
- Revises § 10.30(e)(2) to conform with the addition of § 10.30(e)(5).
- Makes minor revisions to §§ 10.20 and 10.30 to conform to the addition of § 10.31.
- With respect to § 10.35, administrative stay of action, makes revisions to conform with the implementation of section 505(q) of the FD&C Act. The final rule also adds new § 10.35(i) to clarify that a petitioner requesting 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, the final rule makes minor technical changes by revising §§ 10.30(e)(3) and 10.35(e) to allow the

Commissioner to dismiss a petition if changes in law, facts, or circumstances since the date on which the petition was submitted render the petition moot.

B. Significant Changes to the Proposed Rule

The final rule reflects revisions to the proposed rule in response to the enactment of FDASIA. Section 1135 of FDASIA amended section 505(q) of the FD&C Act in several ways. First, it shortened from 180 days to 150 days FDA's deadline for responding to petitions subject to section 505(q) of the FD&C Act. Second, it expanded the scope of section 505(q) of the FD&C Act to include certain petitions related to 351(k) applications. Lastly, FDASIA also added section 505(q)(4)(B) of the FD&C Act, which excludes such petitions from section 505(q)(2).

Accordingly, the final rule includes the following changes to the proposed rule:

- Adds § 10.30(e)(5) and revises § 10.30(e)(2) to reflect FDA's 150-day deadline for responding to petitions subject to section 505(q) of the FD&C Act.
- Revises § 10.31(a)(1) to reflect the applicability of section 505(q) of the FD&C Act to 351(k) applications.

These changes conform the final rule to reflect amendments to section 505(q) of the FD&C Act enacted by FDASIA that became law after publication of the proposed rule.

III. Comments on the Proposed Rule and FDA Responses

A. Introduction

We received one submission containing several comments from the Pharmaceutical Research and Manufacturers of America (PhRMA). These comments primarily focused on the scope of proposed § 10.31 and the certification and verification requirements. PhRMA also

raised several issues we deemed outside the scope of the proposed rule. In the discussion that follows, we address the comments.

We describe and respond to the comments in sections III.B through III.E. We have numbered each comment to help distinguish between different comments. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received.

B. Scope of the Proposed Rule (§ 10.31)

(Comment 1) We received a comment from PhRMA concerning the scope of the rule. PhRMA stated that, in some instances, the rule would require unnecessary certifications for petitions outside the scope of section 505(q) of the FD&C Act that could cause confusion among petitioners, commentators, and the courts regarding which rules to apply to any given petition. PhRMA claimed the proposed rule could compromise a petitioner's fundamental right to know which statutory requirements and timelines FDA will apply to the petition. Accordingly, PhRMA requested that FDA revise the proposed rule to limit the rule's application to cases in which there is evidence that a relevant ANDA or 505(b)(2) application is pending before FDA.

(Response 1) We decline to make this revision. Normally, the existence of a pending application is not made public by FDA. (See e.g., 21 CFR 314.430.) To prevent uncertainty as to when a certification or verification is required and to protect against the unintended release of information acknowledging the existence of an ANDA, a 505(b)(2) application, or a 351(k) application, we are making § 10.31 apply to all petitions that request an action that could delay the approval of an ANDA, a 505(b)(2) application, or a 351(k) application, regardless of whether an application subject to the petition's requested action is pending at the time the petition is submitted. Otherwise, if petitioners were to omit the certification statement and wait for FDA to

inform them that the certification is required (because of the existence of a pending application), the filing of petitions could become a way for individuals to uncover the existence of certain pending applications. Neither FDAAA nor FDASIA suggest such an outcome. Moreover, rather than causing confusion, as PhRMA suggests, we believe that requiring certifications and verifications for all applicable petitions would remove any uncertainty as to whether a petitioner should submit or not submit a certification or verification. If there is no related ANDA, 505(b)(2) application, or 351(k) application pending at the time the petition is submitted, then the requirements of §10.31 will apply to the petition, but we will not consider the provisions of section 505(q) of the FD&C Act to apply to the petition.

C. Certification and Verification Requirements

(Comment 2) PhRMA expressed specific concerns regarding the certification and verification requirements of the rule. First, PhRMA requested that the discretionary language found in the preamble to the proposed rule, i.e., “[t]he 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....”, be clarified to prevent confusion over how FDA intends to interpret and implement the certification and verification requirements. Second, PhRMA questioned FDA’s assertion that a failure to certify or verify a “became known” date would foreclose a petitioner from relying on that information when seeking judicial review. Accordingly, PhRMA requested that FDA: (1) Revise the proposed rule and provide additional explanation and examples to clarify what types of information petitioners must provide “became known” dates for and (2) “provide support for, modify, or expressly withdraw” the preamble statement concerning judicial review.

(Response 2) We recognize that a petition, supplement, or comment could be based on more than one type of information or multiple pieces of information. Section 505(q) of the FD&C Act requires that the petitioner provide in the certification the date on or about which information first became known to the petitioner. We interpret section 505(q) of the FD&C Act to require an on or about date for each piece of information that is relied upon in the petition. Section II.B.7 of the preamble to the proposed rule provides an example illustrating how a petition may list different types of information. A petition, supplement, or comment will meet the certification/verification requirement if it contains a date followed by a short description of the information. This requirement is essential to carrying out the legislative intent of Congress and does not impose an unreasonable burden on petitioners. Because of the fact-based nature of a petition, it is impracticable for FDA to specifically define or categorize all types of information that may be relied upon by a petitioner. A petitioner or commenter can, however, reasonably be expected to identify the main categories of information on which the petition, supplement, or comment relies and to provide dates for such categories. Indeed, this interpretation of the certification has worked well to date. The failure to certify or verify a “became known” date for any item of information contained in a petition would preclude the petitioner from relying on that information when seeking judicial review since section 505(q)(1)(H) and (I) of the FD&C Act requires that FDA not consider and/or accept for review any petition or information that fails to meet the certification and verification requirements.

D. Nonretroactivity of the Rule

(Comment 3) PhRMA expressed concern that the rule could be read as retroactively imposing requirements on petitions filed after September 26, 2007, but before the effective date of the final rule. Based on its concern, PhRMA requested that FDA revise the rule to clarify that

§ 10.31 will not apply to any petition that was pending at FDA before the final rule's effective date, to any supplement to such a petition, or to any comments on such a petition.

(Response 3) FDA's guidance for industry "Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act" (Ref. 1), describes FDA's current thinking on the applicability of section 505(q) to petitions submitted after September 27, 2007. As that guidance notes, section 505(q) of the FD&C Act applies to all petitions that are submitted on or after September 27, 2007 (or July 9, 2012, if the subject matter of the petition relates to the approval of a 351(k) application). To the extent the final rule imposes any additional requirements, those requirements will apply only to those petitions submitted on or after the effective date of the final rule.

E. Additional Comments

(Comment 4) PhRMA requested that FDA include or otherwise establish a mechanism for notifying a petitioner if the Agency determines that a delay of approval of an ANDA or 505(b)(2) application is not necessary to protect the public health.

(Response 4) We decline to implement such a mechanism for notifying petitioners. As PhRMA pointed out, section 505(q) of the FD&C Act does not require such a notification. The only notification provision in section 505(q) of the FD&C Act is found in section 505(q)(1)(B), which requires FDA to inform an ANDA applicant, a section 505(b)(2) applicant, or a 351(k) applicant that a delay in approval is necessary to protect the public health. Moreover, such a notification mechanism would be burdensome for the Agency and could inadvertently inform the public of pending ANDAs, 505(b)(2) applications, or 351(k) applications.

(Comment 5) PhRMA requested that FDA issue a regulation establishing (or clarifying) the administrative consequence of a decision to approve an ANDA or a 505(b)(2) application

prior to making a final decision on a related 505(q) petition (i.e., whether such an approval would be considered a denial of the petition under section 505(q)(2)(A)(i) of the FD&C Act).

(Response 5) We believe the statute clearly defines what constitutes an exhaustion of administrative remedies with regard to section 505(q) petitions. Section 505(q)(2) of the FD&C Act governs judicial review of final Agency action on certain petitions filed under section 505(q). Under section 505(q)(2)(A) of the FD&C Act, FDA is considered to have taken final Agency action on a petition if either: (1) FDA makes a final decision within the meaning of § 10.45(d) during the 150-day period or (2) the 150-day period expires without FDA making a final decision. Section 505(q)(2) of the FD&C Act is silent as to the effect of approving an ANDA or a 505(b)(2) application prior to FDA's action on a petition. In our view, the language of section 505(q)(2) of the FD&C Act is clear and decouples a final action on a petition from a decision on an underlying ANDA or 505(b)(2) application. (We note that petitions addressing issues concerning 351(k) applications are excluded from the scope of section 505(q)(2) of the FD&C Act). Therefore, a decision on an ANDA or a 505(b)(2) application that occurs prior to the issuance of a petition response will not constitute final Agency action on the petition.

(Comment 6) PhRMA requested that FDA issue a regulation establishing (or clarifying) that a delay in approval of an ANDA or a 505(b)(2) application can extend beyond the 180-day (now 150-day) review period for a petition.

(Response 6) We decline to issue a regulation establishing or clarifying that a delay in approval of an ANDA or a 505(b)(2) application can exceed the 150-day review period for petitions. Because of the uncertainty in predicting the time it will take to resolve a particular issue, establishing an expectation on the possible length of a delay would be neither practical nor

feasible. We believe that based on the language of section 505(q) of the FD&C Act, no clarification is necessary.

(Comment 7) Finally, PhRMA requested that FDA abandon its practice of not providing a substantive response to every section 505(q) petition regardless of the review status of a pending ANDA or 505(b)(2) application.

(Response 7) This issue is outside the scope of this rulemaking. FDA's current thinking on this issue is outlined in section III.E of its guidance for industry "Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act" (Ref. 1), and we do not believe further elaboration is necessary.

IV. Legal Authority

This rule amends §§ 10.20, 10.30, and 10.35, and adds § 10.31 in a manner consistent with the Agency's current understanding and application of these provisions. FDA is implementing certain provisions of FDAAA and FDASIA 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)).

V. Analysis of 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.

VI. Economic Analysis of Impacts

A. Introduction and Summary

We have 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 us 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). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule (Ref. 2). We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the annualized compliance costs to industry members, including small entities, is estimated to be slightly above \$100, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "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 \$146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Final Regulatory Impacts Analysis

1. Industry Costs

We estimate one-time costs to industry from this final rule at about \$626,300. We estimate annual costs at about \$1,800. These costs equate to an estimated total annualized cost of about \$91,000 at a 7 percent discount rate over 10 years and about \$75,200 at a 3 percent discount rate over 10 years. The total annualized costs include the administrative cost to review the rule (\$89,200) plus the cost for the additional effort preparing certifications for petitions and verifications for both responses to petitions and supplements to petitions (\$1,800).

2. Benefits

The final rule contains several clarifications to the language provided in FDAAA and small additions to the statute's provisions. It reinforces the need for exact wording of both the certification and verification statements for petitions, supplements to petitions, and responses to petitions. Furthermore, the rule clarifies the exact dating procedures for these documents. By providing additional clarity on the statutory requirements, we expect the final rule will slightly reduce the number of deficient 505(q) petitions. We do not have enough information to estimate this reduction in deficient 505(q) petitions, but the reduction should result in lower administrative costs for both industry and FDA.

The Economic Analysis of Impacts of the final rule, performed in accordance with Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act, is available at <http://www.regulations.gov> under the docket number for this final rule (FDA-2011-N-0697) and at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.

VII. Paperwork Reduction Act of 1995

This final rule contains no new information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520) (the PRA). The final rule refers to previously approved collections of information found in FDA regulations. The collections of information in §§ 10.30 and 10.35 have been approved under OMB control number 0910-0191. The collections of information in § 10.31 have been approved under OMB control number 0910-0679. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910-0001. The certification and verification statements required under § 10.31(c) and (d) are “public disclosure[s] of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public...” (5 CFR 1320.3(c)(2)) and therefore not subject to OMB review.

VIII. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that 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, we conclude that the 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.

IX. References

The following references are on display in the Division of Dockets Management (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m.,

Monday through Friday; they are also available electronically at <http://www.regulations.gov>.

FDA has verified the Web site addresses, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.

1. FDA Guidance for Industry, “Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act,” November 2014, available at <http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm079353.pdf>.

2. Final Regulatory Impact Analysis, “Amendments to Regulations on Citizen Petitions, Petitions for Stay of Action, and Submission of Documents to Dockets,” Docket No. FDA-2011-N-0697, available at

<http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.

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, 21 CFR part 10 is amended as follows:

PART 10--ADMINISTRATIVE PRACTICES AND PROCEDURES

1. The authority citation for 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. In § 10.20, revise 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. Revise the first sentence of paragraph (e)(2);
 - e. Remove from paragraph (e)(2)(ii) the word “or”;
 - f. Redesignate paragraph (e)(2)(iii) as paragraph (e)(2)(iv);
 - g. Add new paragraph (e)(2)(iii);
 - h. Add to paragraph (e)(3) a new sentence after the first sentence; and
 - i. Add new paragraph (e)(5).

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 also be submitted in accordance with the following paragraphs, as applicable:

* * * * *

(c) A petition that appears to meet the requirements of paragraph (b)(3) 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 unique docket number. * * *

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

(e) * * *

(2) Except as provided in paragraphs (e)(4) and (5) of this section, the Commissioner shall furnish a response to each petitioner within 180 days of receipt of the petition.* * *

(iii) Dismiss the petition 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. * * *

* * * * *

(5) The Commissioner intends to furnish a response to each petitioner within 150 days of receipt of a petition subject to section 505(q) of the Federal Food, Drug, and Cosmetic Act.

* * * * *

4. Add § 10.31 to subpart B to read as follows:

§ 10.31 Citizen petitions and petitions for stay of action related to abbreviated new drug applications, certain new drug applications, or certain biologics license applications.

(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 submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act, a new drug application submitted through the pathway described by section 505(b)(2) of the Federal, Food, Drug and Cosmetic Act, or a biologics license application submitted under section 351(k) of the Public Health Service Act.

(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, or § 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: (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 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 first blank space provided. If different categories of information become 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: (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 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 first blank space provided. If different categories of

information become known at different times, the verification must contain each estimated relevant date. The information associated with a particular date must be identified.

5. In § 10.35 revise the third sentence of paragraph (b); in paragraph (e) introductory text add a new sentence after the second sentence; and add 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 a request for stay subject to § 10.31 must also 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. * * *

* * * * *

(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: November 2, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-26912 Filed: 11/7/2016 8:45 am; Publication Date: 11/8/2016]