SUPPORTING STATEMENT

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

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration Amendments Act of 2007 (FDAAA) added new provisions to the Federal Food, Drug, and Cosmetic Act (the act) addressing the agency's treatment of certain citizen petitions and petitions for stay of agency action (collectively, petitions), as well as related applications. The guidance entitled "Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act" describes how FDA will determine if the new provisions apply to a particular petition and how FDA will determine if a petition would delay approval of a pending abbreviated new drug application (ANDA) or 505(b)(2) application. The guidance also describes how FDA will interpret the requirements that such petitions include a certification and that supplemental information or comments to such petitions include a verification. The guidance also 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.

FDAAA was enacted on September 27, 2007. Section 914 of Title IX of FDAAA took effect on the date of enactment and amended section 505 of the Act by adding a new subsection (q). Section 505(q) applies to certain petitions that request that FDA take an form of action related to a pending ANDA or 505(b)(2) application and governs the manner in which these petitions are treated. Section 505(q)(1)(A), together with section 505(q)(5), describes the

general scope of section 505(q). Section 505(q)(1)(A) provides that the Secretary shall not delay approval of a pending application submitted under subsection (b)(2) or (j) because of any request to take any form of action relating to the application, either before or during consideration of the request, unless the request is in writing and is a petition submitted to the Secretary pursuant to section 10.30 or 10.35 of title 21, Code of Federal Regulations (or any successor regulations); and the Secretary determines, upon reviewing the petition, that a delay is necessary to protect the public health. If FDA determines that a delay of approval of an ANDA or 505(b)(2) application is necessary to protect the public health, FDA is required to provide to the applicant not later than 30 days after making the determination: notification that the determination has been made, if applicable, any clarification or additional data that the applicant should submit to the petition docket to allow FDA to review the petition promptly, and a brief summary of the specific substantive issues raised in the petition which form the basis of the determination. At FDA's discretion, the information is to be conveyed by either a document or a meeting with the applicant. The information conveyed as part of the notification is to be considered part of the application and subject to the disclosure requirements applicable to information in such application. Under section 505(q)(1)(H), FDA may not consider a petition for review unless the petition is in writing and signed and contains a certification that is specified in that section. In addition, FDA may not accept for review any supplemental information or comments on a petition unless the submission is in writing and signed and contains a specific verification. Section 505(q)(1)(F) governs the timeframe for final Agency action on a petition. Under this provision, FDA shall take final Agency action on a petition not later than 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, the submission of comments or

supplemental information, or the consent of the petitioner. FDA may deny a petition at any point if the Agency determines that a petition or a supplement to the petition was submitted with the primary purpose of delaying the approval of an application and the petition does not on its face raise valid scientific or regulatory issues. 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)(2) governs judicial review of final Agency action. Under section 505(q)(2)(A), FDA shall be considered to have taken final Agency action on a petition if FDA makes a final decision within the meaning of 21 CFR 10.45(d) during the 180-day period or the 180-day period expires without FDA having made a final decision. Under section 505(q)(2)(B), if a civil action is filed against the Secretary with respect to any issues raised in the petition before final Agency action, a court shall dismiss the action without prejudice for failure to exhaust administrative remedies. Section 505(q)(2)(C) describes the information to be included in the administrative record. Section 505(q)(4) exempts certain categories of petitions from the provisions of section 505(q) — in particular, petitions relating to 180-day generic drug exclusivity and petitions from a 505(b)(2) or ANDA applicant regarding FDA actions with respect to that application. Section 505(q)(3) and section 914(b) of FDAAA also provide for certain reporting requirements from FDA to Congress.

2. <u>Purpose and Use of the Information Collection</u>

The guidance describes FDA's interpretation of section 505(q) of the 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.

3. Use of Improved Information Technology and Burden Reduction

FDA has issued several guidance documents explaining how to submit information to the agency in electronic format. These guidance documents and others are available at FDA's web site http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm064994.htm

4. Efforts to Identify Duplication and Use of Similar Information

This information does not duplicate any other collection.

5. Impact on Small Businesses or Other Small Entities

Under the Regulatory Flexibility Act, FDA regularly analyzes regulatory options that would minimize any significant impact on small entities. FDA also assists small businesses in complying with regulatory requirements.

6. Consequences of Collecting the Information Less Frequently

FDA will be unable to comply with the statutory provisions of FDAAA, which added new provisions to the act addressing the agency's treatment of certain citizen petitions and petitions for stay of agency action (collectively, petitions), as well as related applications. The guidance describes how FDA will determine if the new provisions apply to a particular petition and how FDA will determine if a petition would delay approval of a pending abbreviated new drug application (ANDA) or 505(b)(2) application. The guidance also describes how FDA will interpret the requirements that such petitions include a certification and that supplemental information or comments to such petitions include a verification. The guidance also 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.

7. Special Circumstances Relating to the Guidelines in 5 CFR 1320.5

There is no inconsistency.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In the FEDERAL REGISTER of January 21, 2009 (74 FR 3611), FDA announced the availability of the draft guidance for industry entitled "Draft Guidance for Industry on Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act." FDA is now in the process of finalizing this guidance. In that FEDERAL REGISTER notice, FDA provided the public with 60 days to comment on the proposed collection of information. FDA received no comments pertaining to the information collection

in the draft guidance.

9. Explanation of Any Payment or Gift to Respondents

FDA has not provided and has no intention to provide any payment or gift to respondents under these requirements.

10. Assurance of Confidentiality Provided to Respondents

Confidentiality of the information submitted under this information collection is protected under 21 CFR part 20. The unauthorized use or disclosure of trade secrets required in applications is specifically prohibited under Section 310(j) of the Act.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature.

12a. Estimates of Annualized Hour Burden

Hour Burden

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 petitions for stay of agency action are persons who choose to file a petition for an administrative stay of action.

Section 505(q)(1)(H) of the FD&C Act requires that citizen petitions and petitions for

stay of agency action that are subject to section 505(q) include a certification to be considered for review by FDA. Section 505(q)(1)(I) requires that supplemental information or comments to such citizen petitions and petitions for stay of agency action include a verification to be accepted for review by FDA. This guidance describes our current thinking on the interpretation of these requirements. The guidance sets forth the criteria the agency will use in determining if the provisions of section 505(q) apply to a particular citizen petition or petition for stay of agency action. One of the criteria for a citizen petition or petition for stay of agency action to be subject to section 505(q) of the FD&C Act 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, the guidance recommends that all petitioners challenging the approvability of a possible ANDA or 505(b)(2) application include the certification required in section 505(q)(1)(H) of the FD&C Act and that petitioners and commenters submitting supplements or comments, respectively, to a citizen petition or petition for stay of action challenging the approvability of a possible ANDA or 505(b)(2) application include the verification required in section 505(q)(1)(I) of the FD&C Act. The guidance also recommends that if a petitioner submits a citizen petition or petition for stay of agency action that is missing the required certification but is otherwise within the scope of section 505(q) of the FD&C Act and the petitioner would like FDA to review the citizen petition or petition for stay of agency action, the petitioner should submit a letter withdrawing the deficient petition and submit a new petition that contains the required certification.

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 (21 CFR 10.20), a citizen petition requesting the Commissioner of Food and Drugs (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) (21 CFR 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) (21 CFR 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, petitions for administrative stay of action, comments to petitions, supplements to citizen petitions, and letters to withdraw a citizen petition, as described above, that are subject to section 505(q) of the FD&C Act and described in the guidance.

Under section 505(q) of the FD&C Act and the guidance, the following information would be submitted to FDA but is not currently approved by OMB under the PRA:

1. The certification required under section 505(q)(1)(H) of the FD&C Act for citizen petitions that are subject to section 505(q) and/or that are challenging the approvability of a possible ANDA or 505(b)(2) application. Although the submission of a certification for citizen petitions is approved under OMB Control Number 0910-0183, the certification would be broadened under section 505(q) of the act and the guidance.

2. The certification required under section 505(q)(1)(H) of the FD&C Act for petitions for

stay of agency action that are subject to section 505(q) and/or that are challenging the approvability of a possible ANDA or 505(b)(2) application.

3. The verification required under section 505(q)(1)(I) of the FD&C Act for comments to citizen petitions.

4. The verification required under section 505(q)(1)(I) of the FD&C Act for comments to petitions for stay of agency action.

5. The verification required under section 505(q)(1)(I) of the FD&C Act for supplements to citizen petitions.

6. Supplements to petitions for stay of agency action.

7. The verification required under section 505(q)(1)(I) of the FD&C Act for supplements to petitions for stay of agency action.

8. The letter submitted by a petitioner withdrawing a deficient petition for stay of agency action that is missing the required certification but is otherwise within the scope of section 505(q) of the FD&C Act.

Section 505(q)(1)(B) and (C) of the FD&C Act and the guidance state that if FDA determines that a delay in approval of an ANDA or 505(b)(2) application is necessary based on a petition subject to section 505(q) of the FD&C Act, the applicant may submit to the petition docket clarifications or additional data to allow FDA to review the petition promptly. This information collection is not included in this analysis because it is approved under OMB Control Number 0910-0001 (21 CFR 314.54, 314.94, and 314.102).

Based on FDA's knowledge of citizen petitions and petitions for stay of agency action subject to section 505(q) of the FD&C Act that have been submitted to FDA, as well as the

agency's familiarity with the time needed to prepare a supplement, a certification, and a verification, our estimates for this information collection are as follows:

Table 1. -- Estimated Annual Reporting Burden[1]

	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours
Certification for citizen petitions (505(q)(1)(H))	19	1.32	25	0.5	12.5
Certification for petitions for stay of agency action (505(q)(1)(H))	3	1	3	0.5	1.5
Verification for comments to citizen petitions (505(q)(1)(I))	9	1.33	12	0.5	6.0
Verification for comments to petitions for stay of agency action (505(q)(1)(I))	2	1	2	0.5	1.0
Verification for supplements to citizen petitions (505(q)(1)(I))	7	1.43	10	0.5	5.0
Supplements to petitions for stay of agency action	1	1	1	6	6
Verification for supplements to petitions for stay of agency action (505(q)(1)(I))	1	1	1	0.5	0.5
Letter withdrawing a petition for stay of agency action	1	1	1	0.5	0.5

Total Hours		33

12b. Estimated Annualized Labor costs

Type of Respondent	Total Burden Hours	Hourly Wage	Total Respondent Cost
Pharmaceutical industry average wage grade for preparing and submitting this information collection	33	85.00	$2,805
Total			$2,805

13. Estimates of Other Total Annual Cost Burden to Respondents and Recordkeepers

There are no other costs, including capital costs or operating and maintenance costs associated with this collection of information.

14. Annualized Cost to the Federal Government

There are 55 total annual responses that may result from this guidance (see table above). FDA estimates that, on average, it would take FDA regulatory policy personnel approximately 15 minutes to review each submission. Based on a loaded hourly wage rate of approximately $75.00 per hour, we estimate that the Federal costs would be approximately $1,031.25

15. Explanation for Program Changes or Adjustments

This is a new collection.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA does not intend to publish tabulated results of these information collection requirements.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

All forms associated with this collection will bear the OMB approval date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no certifications required.