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

0910-0679

SUPPORTING STATEMENT

Terms of Clearance – None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

In the Federal Register of June 8, 2011(76 FR 33309), FDA announced the availability of a 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." The guidance provides information regarding FDA's current thinking on interpreting section 914 of Title IX of the Food and Drug Administration Amendments Act (FDAAA) (Pub. L. 110-85). Section 914 of FDAAA added new section 505(q) to the FD&C Act (21 U.S.C. 355(q)) and governs certain citizen petitions and petitions for stay of agency action that request that FDA take any form of action related to a pending application submitted under section 505(b)(2) or 505(j) (U.S.C. 355(b)(2) or U.S.C. 355(j)) of the FD&C Act. 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 abbreviated new drug application (ANDA) or a section 505(b)(2) application. The guidance also describes how FDA will interpret the provisions of section

505(q) requiring that: (1) A petition includes 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 section 505(b)(2) applications for which the Agency has not yet made a decision on approvability.

The Food and Drug Administration Safety and Innovation Act (FDASIA) was signed into law on July 9, 2012 (Pub. L. 112-144, 126 Stat. 993). Section 1135 of FDASIA amended section 505(q) of the FD&C Act in two ways. First, it shortened FDA's deadline from 180 days to 150 days 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 concerning applications submitted under section 351(k) of the Public Health Service Act (42 U.S.C. 262), the abbreviated pathway for the approval of biosimilar biological products. Accordingly, we are now including submissions pertaining to biosimilar biological product applications in the information collection burden estimates below.

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) of the FD&C Act 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. The guidance sets forth the criteria the Agency will use in determining if the provisions of section 505(q) of the FD&C Act apply to a particular citizen petition or petition for stay of agency action. The guidance states that 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 section 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 section 505(b)(2) application, the guidance recommends that all petitioners challenging the approvability of a possible ANDA or section 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 section 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.

2. Purpose and Use of the Information Collection

The guidance describes, among other things, how FDA will determine whether 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 whether a petition would delay approval of a pending ANDA or a 505(b)(2) application. The guidance also describes the provisions of section 505(q) requiring that a petition include a certification and that supplemental information or comments to a petition include a verification.

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 are no special circumstances for this collection of information.

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

In the Federal Register of October 1, 2013 (78 FR 60288), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received no comments pertaining to the information collection.

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.

12. Estimates of Annualized Burden Hours and Costs

12a. Estimates of Annualized 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 previously in this document, which are subject to section 505(q) of the FD&C Act and described in the guidance.

We are requesting OMB approval for the following collection of information submitted to FDA under section 505(q) of the FD&C Act and the guidance:

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, section 505(b)(2) application, or biosimilar biological product 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 FD&C 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, section 505(b)(2) application, or biosimilar biological product 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, section 505(b)(2) application, or biosimilar biological product application is necessary based on a petition subject to section 505(q), 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.

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, FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden

Activity	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden Per Response	Total Hours
Certification for citizen petitions (505(q)(1)(H))	26	1.15	32	0.5 (30 min.)	16
Certification for petitions for stay of agency action (505(q)(1)(H))	1	1	1	0.5 (30 min.)	.5
Verification for comments to citizen petitions (505(q)(1)(I))	9	1.33	12	0.5 (30 min.)	6.0
Verification for comments to petitions for stay of agency action (505(q)(1)(I))	1	1	1	0.5 (30 min.)	.5
Verification for supplements to citizen petitions (505(q)(1)(I))	7	1.43	10	0.5 (30 min.)	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 (30 min.)	0.5
Letter withdrawing a	1	1	1	0.5	0.5

petition for stay of agency action				(30 min.)	
Total Hours					35

12b. Estimated Annualized Labor Costs

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Pharmaceutical industry average wage grade for preparing and submitting this information collection	35	85.00	$2,975

13. Estimates of Other Total Annual Cost Burden to Respondents and/or Recordkeepers/Capital Costs

There are no other capital, start-up, operating or maintenance costs associated with this collection of information.

14. Annualized Cost to the Federal Government

There are 59 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 $1,125.

15. Explanation for Program Changes or Adjustments

There is a slight increase in burden based on current submissions.

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 exceptions to the certification.