FOOD AND DRUG ADMINISTRATION
Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q)
of the Federal Food, Drug, and Cosmetic Act.
OMB Control No. 0910-0679

SUPPORTING STATEMENT

Terms of Clearance – None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The information collection supports the filing of certain petitions, and Food and Drug Administration (FDA) guidance entitled "*Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act.*" Specifically, 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 Federal Food, Drug, and Cosmetic Act (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) (21 U.S.C. 355(b)(2) or 21 U.S.C. 355(j)) of the FD&C Act. The guidance also describes FDA's interpretation of section 505(q) of the FD&C Act regarding how the agency will determine: (1) if 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) if a petition would delay approval of a pending abbreviated new drug application (ANDA) or a 505(b)(2) application. The guidance also describes how FDA will interpret the provisions of section 505(q) requiring that a petition includes a certification and 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.

The FD&C Act was also amended by the Food and Drug Administration Safety and Innovation Act (FDASIA) (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 (PHS) Act (42 U.S.C. 262), the abbreviated pathway for the approval of biosimilar biological products. Accordingly, submissions pertaining to biosimilar biological product applications are also included in the information collection.

Finally, 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 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.

Accordingly, we are requesting OMB approval for the information collection provisions covered by the FD&C Act regarding petitions submitted to FDA under section 505(q) of the FD&C Act and discussed in agency guidance, including:

- 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, 505(b)(2) application, or biosimilar biological product application. Although the submission of a certification for citizen petitions is approved under OMB Control Number 0910-0191, the certification would be broadened under section 505(q) of the FD&C Act and the guidance.

- 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, 505(b)(2) application, or biosimilar biological product application.

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

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

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

- Supplements to petitions for stay of agency action.

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

- 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.

2. Purpose and Use of the Information Collection

As explained in our guidance, we will use the information collection to 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.

3. Use of Improved Information Technology and Burden Reduction

FDA encourages the use of information technology. We have issued industry guidance regarding how to submit information to the agency in electronic format. These guidance documents and others are available at FDA's Website http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm064994.htm

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. While the agency has established information collection associated with citizen petitions filed under 21 CFR Part 10 (approved under OMB Control No. 0910-0191), this information collection supports information collection associated with petitions subject to section 505(q) of the FD&C Act and as discussed in the associated guidance.

5. Impact on Small Businesses or Other Small Entities

The information collection requirements apply to all respondents alike. FDA provides small business assistance information on its Website at: http://www.fda.gov/ForIndustry/SmallBusinessAssistance/SmallBusinessRepresentatives/guidance, and within various agency components including the Center for Drug Evaluation and Research's (CDER) Small Business and Industry Assistance Office (SBIA), available at:

CDER SBIA

Office of Communications
10001 New Hampshire Avenue
Hillandale Building, 4th Floor
Silver Spring, MD 20993
(866) 405-5367
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6. Consequences of Collecting the Information Less Frequently

Information collection schedule is consistent with existing statutory requirements regarding the filing of subject petitions under the FD&C Act.

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 January 10, 2017 (82 FR 2999), we requested comments on the proposed collection of information. No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No gifts or payment is provided to respondents to the information collection.

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 FD&C 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 information collection are individuals or households, State or local governments, not-for-profit institutions, and businesses or other for-profit institutions or groups, or anyone who chooses to file a petition for an administrative stay of action. In a related information collection (OMB Control No. 0910-0191) entitled, "*General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions*," FDA has OMB approval of the information collection requirements found under 21 CFR Part 10, including:

(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 covers the requirements for citizen petitions, petitions for administrative stay of action, comments to petitions, supplements to citizen petitions, and letters to withdraw a citizen petition, as described in the FDA guidance regarding filings subject to section 505(q) of the FD&C Act. Section 505(q)(1)(B) and (C) of the FD&C Act and FDA guidance state that if FDA determines that a delay in approval of an ANDA, 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 promptly review the petition. 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 our 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, as well as our familiarity with the time needed to prepare a supplement, a certification, and a verification, we estimate the

burden of the collection of information as follows:

Table 1 – Estimated Annual Reporting Burden[1]

Petition Requirement	No. of respondents	No. of responses per respondent	Total annual responses	Avg. burden per response	Total hours
Certification for citizen petitions; 505(q)(1)(H)	38	1.37	52	0.5	26
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)	12	1.66	20	0.5	10
Verification for comments to petitions for stay of agency action; 505(q)(1)(I)	1	1	1	0.5	.5
Verification for supplements to citizen petitions; 505(q)(1)(I))	7	2.29	16	0.5	8
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	3	1	3	0.5	1.5
Total Hours					54

[1] There are no capital or operating and maintenance costs associated with the collection of information.

12b. Estimate of Annualized Cost Burden

We estimate no annualized cost burden to respondents for the collection of information.

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

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

14. Annualized Cost to the Federal Government

Using the 54 burden hours for respondents, we estimate it takes FDA regulatory policy personnel approximately 15 minutes (.25/hr) to review each submission. Multiplying that rate by a loaded hourly wage rate of $75.00 per hour, the cost to the Federal government is approximately $1,012.50.

15. Explanation for Program Changes or Adjustments

We have adjusted our estimate to reflect a nominal increase in the number of annual submissions, based on a review of agency data. Corresponding adjustments reflect an increase of 40 annual responses and 20 burden hours.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA has no plans for tabulation or publication of the information collection.

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

Display of OMB Expiration Date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.