Dated: April 19, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0008]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 25, 2017.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0679. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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—OMB Control Number 0910–0679—Extension

FDA's 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'' 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 (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) 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 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 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). 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 in this document.

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.

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 0910–0191). 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:

- 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.

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, 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. While we have not included a burden estimate for this provision under the instant information collection, it is included under OMB control number 0910–0001 (21 CFR 314.54, 314.94, and 314.102).

In the **Federal Register** of January 10, 2017 (82 FR 2999), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. No comments were received in response to the notice. Therefore, 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 to FDA, as well as our familiarity with the time needed to prepare a supplement, a certification, and a verification, we estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/FD&C Act section	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)	38	1.37	52	.5 (30 minutes)	26
Certification for petitions for stay of Agency action; 505(q)(1)(H).	3	1	3	.5 (30 minutes)	1.5
Verification for comments to citizen petitions; 505(q)(1)(I).	12	1.66	20	.5 (30 minutes)	10
Verification for comments to petitions for stay of Agency action; 505(q)(1)(I).	1	1	1	.5 (30 minutes)	.5
Verification for supplements to citizen petitions; 505(q)(1)(I).	7	2.29	16	.5 (30 minutes)	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	.5 (30 minutes)	.5
Letter withdrawing a petition for stay of Agency action.	3	1	3	.5 (30 minutes)	1.5
Total Hours					54

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

Dated: April 18, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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