4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 10

[Docket No. FDA 2013-S-0610]

Citizen Petition Submission; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is modernizing its administrative regulations regarding submission of citizen petitions to explicitly provide for electronic submission. The current regulation does not recognize electronic methods for submitting citizen petitions; thus, this action will enable efficiency and ease in the filing of citizen petitions.

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

FOR FURTHER INFORMATION CONTACT: Lisa M. Helmanis, Office of Policy, Regulations Policy Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-9135.

SUPPLEMENTARY INFORMATION: FDA is updating its administrative regulations in 21 CFR part 10 to include an electronic method for citizen petition submissions and to remove references only to written documents. The Agency still allows for non-electronic submissions, however, electronic submissions of a citizen petition to a specific electronic docket presents a simpler and straightforward approach. FDA has created a single docket on http://www.regulations.gov, the U.S. Government's consolidated docket Web site for Federal

Agencies, for the initial electronic submission of all citizen petitions. The FDA Electronic Method for Submission of Citizen Petitions Docket, Docket No. FDA 2013-S-0610, allows the petitioner to create an electronic submission through http://www.regulations.gov and provides an alternative to the current system of submission for citizen petitions. Electronic submissions through http://www.regulations.gov will provide the submitter with an immediate record of the time of submission. FDA's Division of Dockets Management (DDM) (http://www.fda.gov/RegulatoryInformation/Dockets/default.htm) will continue to inform the submitter of formal filing; however, tracking will be more easily accomplished through electronic submission.

DDM will receive the electronically submitted citizen petition through the Federal Dockets Management System, the Agency component of http://www.regulations.gov. Subsequently, DDM will review the electronic submission and when it accepts the citizen petition for filing, DDM will assign a docket number to that petition, different from the FDA electronic submission docket number. This unique docket number from DDM identifies the docket for that particular citizen petition for all future filings and submissions related only to that citizen petition. Subsequent submissions associated with that citizen petition will refer to the assigned unique docket number. The advantage to this change is that it ensures efficiency and ease in communication, quicker interaction between citizen petitioners and FDA, and easier access to FDA to seek input through the citizen petition process.

Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that good cause exists to dispense with prior notice and public comment under 5 U.S.C. 553(b)(3)(B) since such notice and comment are unnecessary because this amendment to the regulation provides only technical and grammatical corrections,

modernizes the administrative process to add a simple and electronic method, ensures clarity in the Agency's regulations, and updates obsolete information.

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 21 CFR 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, 236b, 264.

2. Amend § 10.30 by revising paragraphs (b), (c), (d), (e)(3), and (g) to read as follows:

§ 10.30 Citizen petition.

* * * * *

(b) A petition (including any attachments) must be submitted in accordance with the following paragraphs, as applicable:

(1) Electronic submission. Petitions (including any attachments) may be electronically submitted in accordance with paragraph (b)(3) of this section and § 10.20 through http://www.regulations.gov at Docket No. FDA 2013-S-0610. It is only necessary to submit one copy.

(2) Mail, delivery services, or other non-electronic submissions. A petition (including any attachments), that is not electronically submitted under paragraph (b)(1) of this section, must be submitted in accordance with paragraph (b)(3) and § 10.20 and delivered to this address:

Division of Dockets Management, Department of Health and Human Services, Food and Drug Administration,5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

It is only necessary to submit two copies.

(3) Petition format. A petition submitted under paragraphs (b)(1) or (b)(2) of this section must be in accordance with § 10.20 and in the following format:

Citizen Petition

Date:_____

The undersigned submits this petition under ___ (relevant statutory sections, if known) of the ___ (Federal Food, Drug, and Cosmetic Act or the Public Health Service Act or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs) to request the Commissioner of Food and Drugs to ___ (issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action).

A. Action requested

((1) If the petition requests the Commissioner to issue, amend, or revoke a regulation, the exact wording of the existing regulation (if any) and the proposed regulation or amendment requested.)

((2) If the petition requests the Commissioner to issue, amend, or revoke an order, a copy of the exact wording of the citation to the existing order (if any) and the exact wording requested for the proposed order.)

((3) If the petition requests the Commissioner to take or refrain from taking any other form of administrative action, the specific action or relief requested.)

B. Statement of grounds

(A full statement, in a well-organized format, of the factual and legal grounds on which the petitioner relies, including all relevant information and views on which the petitioner relies, as well as representative information known to the petitioner which is unfavorable to the petitioner's position.)

C. Environmental impact

(A) Claim for categorical exclusion under §§ 25.30, 25.31, 25.32, 25.33, or § 25.34 of this chapter or an environmental assessment under § 25.40 of this chapter.)

D. Economic impact

(The following information is to be submitted only when requested by the Commissioner following review of the petition: A statement of the effect of requested action on: (1) Cost (and price) increases to industry, government, and consumers; (2) productivity of wage earners, businesses, or government; (3) competition; (4) supplies of important materials, products, or services; (5) employment; and (6) energy supply or demand.)

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

(Signature) _____

(Name of petitioner) _____

(Mailing address) _____

(Telephone number) _____

(c) A petition which appears to meet the requirements of paragraph (b)(3) of this section and § 10.20 will be filed by the Division of Dockets Management with the date of filing and assigned a unique docket number. The unique docket number identifies the docket file established by the Division of Dockets Management for all submissions relating to the petition, as provided in this part. Subsequent submissions relating to the matter must refer to the assigned docket number assigned in this paragraph and will be filed in the established docket file. Related petitions may be filed together and given the same docket number. The Division of Dockets Management will promptly notify the petitioner of the filing and unique docket number of the petition.

(d) An interested person may submit comments to the Division of Dockets Management on a filed petition, which comments become part of the docket file. The comments are to specify the docket number of the petition and may support or oppose the petition in whole or in part. A request for alternative or different administrative action must be submitted as a separate petition.

(e) * * *

(3) The Commissioner may grant or deny such a petition, in whole or in part, and may grant such other relief or take other action as the petition warrants. The petitioner is to be notified of the Commissioner's decision. The decision will be placed in the public docket file and may also be in the form of a notice published in the Federal Register.

* * * * *

(g) A petitioner may supplement, amend, or withdraw a petition without Agency approval and without prejudice to resubmission at any time until the Commissioner rules on the petition, unless the petition has been referred for a hearing under parts 12, 13, 14, or 15 of this chapter. After a ruling or referral, a petition 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.

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Dated: December 13, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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