§ 10.75 Internal agency review of decisions.

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(e) Each request by an interested person for review of a decision within the Center for Devices and Radiological Health shall also comply with § 800.75 of this chapter.

PART 800—GENERAL

■ 3. The authority citation for part 800 is revised to read as follows:

Authority: 5 U.S.C. 551–559; 21 U.S.C. 301–399f.

■ 4. In part 800, add § 800.75 to subpart C to read as follows:

§ 800.75 Requests for supervisory review of certain decisions made by the Center for Devices and Radiological Health.

(a) The following definitions shall apply to this section:

(1) *FDA* means the Food and Drug Administration.

(2) *517A decision* means a significant decision made by the Center for Devices and Radiological Health, as set forth in section 517A of the Federal Food, Drug, and Cosmetic Act, and includes one of the following decisions:

(i) A substantially equivalent order under § 807.100(a)(1) of this chapter, or a not substantially equivalent order under § 807.100(a)(2) of this chapter;

(ii) An approval order under § 814.44(d) of this chapter, an approvable letter under § 814.44(e) of this chapter, a not approvable letter under § 814.44(f) of this chapter, or an order denying approval under § 814.45 of this chapter;

(iii) An approval order under § 814.116(b) of this chapter, an approvable letter under § 814.116(c) of this chapter, a not approvable letter under § 814.116(d) of this chapter, or an order denying approval under § 814.118 of this chapter;

(iv) A grant or denial of a request for breakthrough device designation under section 515C of the Federal Food, Drug, and Cosmetic Act;

(v) An approval order under § 812.30(a) of this chapter or a disapproval order under § 812.30(c) of this chapter;

(vi) A failure to reach agreement letter under section 520(g)(7) of the Federal Food, Drug, and Cosmetic Act; or

(vii) A clinical hold determination under section 520(g)(8) of the Federal Food, Drug, and Cosmetic Act.

(3) *CDRH* means the Center for Devices and Radiological Health.

(b) Submission of request.

(1) Review of 517A decisions.

(i) An initial or sequential request for supervisory review within CDRH of a 517A decision under § 10.75 of this chapter must be addressed to the next organizational level or higher above the individual who made the decision; submitted in electronic format in accordance with section 745A(b) of the Federal Food, Drug, and Cosmetic Act; marked ''Appeal: Request for Supervisory Review;'' and received by CDRH no later than 30 days after the date of the decision involved. Any such request for supervisory review not received by CDRH within 30 days after the date of the decision involved is not eligible for review. Except as provided in paragraph (b)(1)(ii) or (iii) of this section, FDA will render a decision within 45 days of the request for supervisory review.

(ii) A person requesting supervisory review under paragraph (b)(1)(i) may request an in-person meeting or teleconference with the supervisor reviewing the request for supervisory review. Except as provided in paragraph (b)(1)(iii) of this section, if a request for in-person meeting or teleconference is included in the request for supervisory review to CDRH, CDRH will schedule the meeting or teleconference to occur within 30 days of receipt of the request. Except as provided in paragraph (b)(1)(iii) of this section, a decision will be rendered within 30 days of such meeting or teleconference.

(iii) The timeframes for CDRH to render a decision provided in (b)(1)(i) and (ii), and the timeframe to schedule an in-person meeting or teleconference review in (b)(1)(ii) of this section do not apply, if a matter related to the 517A decision under review is referred by CDRH to external experts, such as an advisory committee, as provided in § 10.75(b) of this chapter.

(2) An initial or sequential request for supervisory review within CDRH under § 10.75 of this chapter of a decision other than a 517A decision that is not received by CDRH within 60 days after the date of the decision involved will be denied as untimely, unless CDRH, for good cause, permits the request to be filed after 60 days. An initial or sequential request for supervisory review within CDRH of a decision other than a 517A decision must be addressed to the next organizational level or higher above the individual who made the decision; submitted in electronic format in accordance with section 745A(b) of the Federal Food, Drug, and Cosmetic Act, when applicable; marked, ''Appeal: Request for Supervisory Review'' in the subject line of the electronic request; and sent to the CDRH Ombudsman at *CDRHOmbudsman@fda.hhs.gov.*

Dated: January 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–00646 Filed 1–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2017–N–0763]

RIN 0910–AH43

Food Labeling: Health Claims; Soy Protein and Coronary Heart Disease; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the proposed rule that appeared in the **Federal Register** of October 31, 2017. We are taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the proposed rule published on October 31, 2017 (82 FR 50324). Submit either electronic or written comments by March 19, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 19, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of March 19, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any

confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–N–0763 for ''Food Labeling: Health Claims; Soy Protein and Coronary Heart Disease.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Crystal Rivers, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1444.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 31, 2017, FDA published a proposed rule to revoke our regulation authorizing the use of health claims on the relationship between soy protein and coronary heart disease on the label or in the labeling of foods. We proposed this action based on our review of the totality of publicly available scientific evidence currently available and our tentative conclusion that such evidence does not support our previous determination that there is significant scientific agreement among qualified experts for a health claim regarding the relationship between soy protein and reduced risk of coronary heart disease. We provided a 75-day comment period for the proposed rule.

We have received requests for a 60-day extension of the comment period for the proposed rule. Each request conveyed concern that the current comment period does not allow sufficient time to develop a meaningful or thoughtful response to the proposed rule.

FDA has considered the requests and is extending the comment period for the proposed rule until March 19, 2018. We believe that this extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

Dated: January 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–00683 Filed 1–12–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2017–1058]

RIN 1625–AA00

Safety Zone; Lower Mississippi River, New Orleans, LA

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish two temporary safety zones for multiple locations and dates within the Captain of the Port Sector New Orleans Zone. These safety zones are necessary to protect persons and vessels from potential safety hazards associated with fireworks displays on or over navigable waterways. Entry into these zones is prohibited unless specifically authorized by the Captain of the Port Sector New Orleans (COTP) or a designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before March 19, 2018.

ADDRESSES: You may submit comments identified by docket number USCG–2017–1058 using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Lieutenant Commander (LCDR) Howard Vacco, Sector New Orleans, US Coast Guard; telephone 504–365–2281, email *Howard.K.Vacco@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port Sector New Orleans
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section