(ii) For the final results of an administrative review, new shipper review, changed circumstances review, or section 762 review, 30 days after the date of publication of the preliminary results of review, unless the Secretary alters the time limit; or

(iii) For the final results of an expedited sunset review, expedited antidumping or countervailing duty review, Article 8 violation review, Article 4/Article 7 review, or section 753 review, a date specified by the Secretary.

(2) The case brief must present all arguments that continue in the submitter's view to be relevant to the Secretary's final determination or final results, including any arguments presented before the date of publication of the preliminary determination or preliminary results. As part of the case brief, parties are encouraged to provide a summary of the arguments not to exceed five pages and a table of statutes, regulations, and cases cited.

(d) *Rebuttal brief.* (1) Any interested party or U.S. Government agency may submit a ''rebuttal brief'' within five days after the time limit for filing the case brief, unless the Secretary alters this time limit.

(2) The rebuttal brief may respond only to arguments raised in case briefs and should identify the arguments to which it is responding. As part of the rebuttal brief, parties are encouraged to provide a summary of the arguments not to exceed five pages and a table of statutes, regulations, and cases cited.

(e) *Word limits.* (1) Except with the consent of Enforcement & Compliance for good cause, each party shall use no more than 25,000 words total between its case and rebuttal briefs. The allocation of the 25,000 words between case and rebuttal briefs is left to each party. All attachments to such briefs, headings, footnotes, endnotes, and quotations shall be included in the word limitation. The summary of arguments and the table of statutes, regulations and cases cited referenced in paragraphs (c)(2) and (d)(2) of this section shall not be included in the word limitation.

(2) The case brief, if any, shall contain a certification by the party or its representative indicating the number of words in the brief and the number of words available for the rebuttal brief. The rebuttal brief, if any, shall contain a certification by the party or its representative indicating the number of words in the brief and certifying that the total word limit of 25,000 has not been exceeded in the party's combined case and rebuttal brief word limit. The party filing the certification may rely on the word count of the software program used to prepare the brief. Briefs in excess of the word limitation shall be rejected and shall be considered untimely. Challenges to opposing party's word count must be filed with the agency within 48 hours of the filing of the case or reply brief and accompanying certifications or the challenge will not be considered. If a person has designated an agent to receive service that is located outside the United States, and served briefs by first class airmail in accordance with 19 CFR 351.303(f)(3)(i), the agency will consider on a case-by-case basis the time allowed to that person to challenge a party's word count.

(f) *Comments on adequacy of response and appropriateness of expedited sunset review*—(1) *In general.* Where the Secretary determines that respondent interested parties provided inadequate response to a notice of initiation (see § 351.218(e)(1)(ii)) and has notified the International Trade Commission as such under § 351.218(e)(1)(ii)(C), interested parties (and industrial users and consumer organizations) that submitted a complete substantive response to the notice of initiation under § 351.218(d)(3) may file comments on whether an expedited sunset review under section 751(c)(3)(B) of the Act and § 351.218(e)(1)(ii)(B) or (C) is appropriate based on the adequacy of responses to the notice of initiation. These comments may not include any new factual information or evidence (such as supplementation of a substantive response to the notice of initiation) and are limited to five pages.

(2) *Time limit for filing comments.* Comments on adequacy of response and appropriateness of expedited sunset review must be filed not later than 70 days after the date publication in the **Federal Register** of the notice of initiation.

[FR Doc. 2016–11864 Filed 5–19–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 175, 176, 177, and 178

[Docket No. FDA–2016–F–1253]

Breast Cancer Fund, Center for Environmental Health, Center for Food Safety, Center for Science in the Public Interest, Clean Water Action, Consumer Federation of America, Earthjustice, Environmental Defense Fund, Improving Kids' Environment, Learning Disabilities Association of America, and Natural Resources Defense Council; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by Breast Cancer Fund, Center for Environmental Health, Center for Food Safety, Center for Science in the Public Interest, Clean Water Action, Consumer Federation of America, Earthjustice, Environmental Defense Fund, Improving Kids' Environment, Learning Disabilities Association of America, and Natural Resources Defense Council proposing that we amend and/or revoke specified regulations to no longer provide for the food contact use of specified ortho-phthalates.

DATES: The food additive petition was filed on April 12, 2016. Submit either electronic or written comments by July 19, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, 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–2016–F–1253 for ''Breast Cancer Fund, Center for Environmental Health, Center for Food Safety, Center for Science In The Public Interest, Clean Water Action, Consumer Federation of America, Earthjustice, Environmental Defense Fund, Improving Kids' Environment, Learning Disabilities Association of America, and Natural Resources Defense Council; Filing of Food Additive Petition.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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.'' The Agency will review this copy, including the claimed confidential information, in its 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kelly Randolph, Center for Food Safety and Applied Nutrition (HFS–275), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 240–402–1188.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 409(b)(5) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348(b)(5)), we are giving notice that we have filed a food additive petition (FAP 6B4815), submitted by Breast Cancer Fund, Center for Science in the Public Interest, Center for Environmental Health, Center for Food Safety, Clean Water Action, Consumer Federation of America, Earthjustice, Environmental Defense Fund, Improving Kids' Environment, Learning Disabilities Association of America, and Natural Resources Defense Council, c/o Mr. Thomas Neltner, 1875 Connecticut Ave. NW., Suite 600, Washington, DC 20009. The submission proposes that we amend and/or revoke specified food additive regulations under 21 CFR parts 175, 176, 177, and 178 to no longer provide for the food contact use of specified ortho-phthalates. We have filed this portion of the submission as a food additive petition. The submission also requests that we amend our regulations in 21 CFR part 181 related to prior-sanctioned uses of specified ortho-phthalates and issue a new regulation in 21 CFR part 189 prohibiting the use of eight specific ortho-phthalates. We have declined to file these portions of the submission as a food additive petition.

II. Amendment of 21 CFR Parts 175, 176, 177, and 178

In accordance with the procedures for amending or revoking a food additive regulation in § 171.130 (21 CFR 171.130), the petition asks us to amend parts 175, 176, 177, and 178 to no longer provide for the food contact use of certain specified ortho-phthalates. The specified ortho-phthalates and corresponding regulations in parts 175, 176, 177, and 178 are as follows:

§ 175.105 Adhesives

Butyl benzyl phthalate (CAS No. 85–68–7), Butyldecyl phthalate (CAS No. 89–19–0), Butyloctyl phthalate (CAS No. 84–78–6), Butyl phthalate butyl glycolate (CAS No. 85–70–1), Di(butoxyethyl) phthalate (CAS No.117–83–9), Dibutyl phthalate (CAS No. 84–74–2), Dicyclohexyl phthalate (CAS No. 84–61–7), Di(2-ethylhexyl)hexahydrophthalate, Di(2-ethylhexyl)phthalate (CAS No. 117–81–7), Diethyl phthalate (CAS No. 84–66–2), Dihexyl phthalate (CAS No. 84–75–3), Dihydroabietylphthalate (CAS No. 26760–71–4), Diisobutyl phthalate (CAS No. 84–69–5), Diisodecyl phthalate (CAS No. 26761–40–0), Diisooctyl phthalate (CAS No. 27554–26–3), Dimethyl phthalate (CAS No. 131–11–3), Dioctyl phthalate (CAS No. 117–84–0), Diphenyl phthalate (CAS No. 84–62–8), Ethyl phthalyl ethyl glycolate (CAS No. 84–72–0), Methyl phthalyl ethyl glycolate (CAS No. 85–71–2), Octyldecyl phthalate (CAS No. 119–07–3), and Diallyl phthalate (CAS No. 131–17–9).

§ 175.300 Resinous and Polymeric Coatings

Dibutyl phthalate (CAS No. 84–74–2), Diethyl phthalate (CAS No. 84–66–2), Diisooctyl phthalate (CAS No. 27554–26–3), Di(2-ethylhexyl) phthalate (CAS No. 117–81–7), and Diisodecyl phthalate (CAS No. 26761–40–0).

§ 175.320 Resinous and Polymeric Coatings for Polyolefin Films

Butyl phthalyl butyl glycolate (CAS No. 85–70–1), Diethyl phthalate (CAS No. 84–66–2), and Ethyl phthalyl ethyl glycolate (CAS No. 84–72–0).

§ 176.170 Components of Paper and Paperboard in Contact With Aqueous and Fatty Foods

Butylbenzyl phthalate (CAS No. 85–68–7), Dibutyl phthalate (CAS No. 84–74–2), Dicyclohexyl phthalate (CAS No. 84–61–7), and Diallyl phthalate (CAS No. 131–17–9).

§ 176.180 Components of Paper and Paperboard in Contact With Dry Food

Butyl benzyl phthalate (CAS No. 85–68–7) and Diallyl phthalate (CAS No. 131–17–9).

§ 176.210 Defoaming Agents Used in the Manufacture of Paper and Paperboard

Di(2-ethylhexyl) phthalate (CAS No. 117–81–7).

§ 176.300 Slimicides

Dibutyl phthalate (CAS No. 84–74–2), Didecyl phthalate (CAS No. 84–77–5), and Dodecyl phthalate (CAS No. 21577–80–0).

§ 177.1010 Acrylic and Modified Acrylic Plastics, Semirigid and Rigid

Di(2-ethylhexyl) phthalate (CAS No. 117–81–7) and Dimethyl phthalate (CAS No. 131–11–3).

§ 177.1200 Cellophane

Castor oil phthalate with adipic acid and fumaric acid diethylene glycol polyester (CAS No. 68650–73–7), Castor oil phthalate, hydrogentated (FDA No. 977037–59–4), Dibutylphthalate (CAS No. 84–74–2), Dicyclohexyl phthalate (CAS No. 84–61–7), Di(2-ethylhexy) phthalate (CAS No. 117–81–7), Diisobutyl phthalate (CAS No. 84–69–5), and Dimethylcyclohexyl phthalate (CAS No. 1322–94–7).

§ 177.1210 Closures With Sealing Gaskets for Food Containers

Diisodecyl phthalate (CAS No. 26761–40–0).

§ 177.1460 Melamine-Formaldehyde Resins in Molded Articles

Dioctyl phthalate (CAS No. 117–84–0).

§ 177.1590 Polyester Elastomers

Dimethyl orthophthalate (CAS No. 131–11–3).

§ 177.2420 Polyester Resins, Cross-Linked

Butyl benzyl phthalate (CAS No. 85–68–7), Dibutyl phthalate (CAS No. 84–74–2), and Dimethyl phthalate (CAS No. 131–11–3).

§ 177.2600 Rubber Articles Intended for Repeated Use

Diphenylguanidine phthalate (CAS No. 17573–13–6), Amyl decyl phthalate (CAS No. 7493–81–4), Dibutyl phthalate (CAS No. 84–74–2), Didecyl phthalate (CAS No. 84–77–5), Diisodecyl phthalate (CAS No. 26761–40–0), Dioctyl phthalate (CAS No. 117–84–0), and Octyl decyl phthalate (CAS No. 119–07–3).

§ 178.3740 Plasticizers in Polymeric Substances

Butylbenzyl phthalate (CAS No. 85–68–7), Dicyclohexyl phthalate (CAS No. 84–61–7), Diisononyl phthalate (CAS No. 28553–12–0), Dihexyl phthalate (CAS No. 84–75–3), and Diphenyl phthalate (CAS No. 84–62–8).

§ 178.3910 Surface Lubricants Used in the Manufacture of Metallic Articles

Diisodecyl phthalate (CAS No. 26761–40–0), Di(2-ethylhexyl) phthalate (CAS No. 117–81–7), and Diethyl phthalate (CAS No. 84–66–2).

The petitioners request FDA to consider that ortho-phthalates are a class of chemically and pharmacologically related substances, and state that there is no longer a reasonable certainty of no harm for the food contact uses of the specified ortho-phthalates. If we determine that new data are available that justify amending the specified food additive regulations in parts 175, 176, 177, and 178 so that they will no longer provide for the use of the ortho-phthalates, we will publish such an amendment of these regulations in the **Federal Register**, as set forth in § 171.130 and § 171.100 (21 CFR 171.100).

III. Amendment of 21 CFR 181.27

A portion of the submission relates to uses of five ortho-phthalates that are listed in § 181.27 as prior-sanctioned. Those five ortho-phthalates are as follows: Diethyl phthalate (CAS No. 84–66–2), Ethyl phthalyl ethyl glycolate (CAS No. 84–72–0), Butyl phthalyl butyl glycolate (CAS No. 85–70–1), Diisooctyl phthalate (CAS No. 27554–26–3), and Di(2-ethylhexyl) phthalate (CAS No. 117–81–7). FDA has not filed as part of the food additive petition the request to revoke these prior sanctions. Section 201(s) of the FD&C Act exempts prior-sanctioned materials from the definition of a food additive (21 U.S.C. 321(s)). Therefore, the request to revoke the prior-sanction for these substances is not within the scope of a food additive petition under section 409(b) of the FD&C Act (''a petition proposing the issuance of a regulation prescribing the conditions under which such [food] additive may be safety used''). We have informed petitioners that they may submit a citizen petition under 21 CFR 10.30 requesting that FDA take this action.

IV. New Regulation in 21 CFR Part 189

A portion of the submission requests that FDA prohibit the food contact use of the following eight ortho-phthalates: Diisobutyl phthalate (CAS No. 84–69–5), Di-n-butyl phthalate (CAS No. 84–74–2), Butyl benzyl phthalate (CAS No. 85–68–7), Dicyclohexyl phthalate (CAS No. 84–61–7), Di-n-hexyl phthalate (CAS No. 84–75–3), Diisooctyl phthalate (CAS No. 27554–26–3), Di(2-ethylhexyl) phthalate (CAS No. 117–81–7), and Diisononyl phthalate (CAS No. 28553–12–0). The submission requests that FDA take this action by issuing a new regulation in part 189. FDA has not filed as part of the food additive petition the request to issue the proposed regulation in part 189. Such a request is not within the scope of a food additive petition under section 409(b) of the FD&C Act (''a petition proposing the issuance of a regulation prescribing the conditions under which such [food] additive may be safety used''). We have informed petitioners that they may submit a citizen petition under 21 CFR 10.30 requesting that FDA take this action.

We also are reviewing the potential environmental impact of the petitioners' requested action. The petitioners have claimed a categorical exclusion from preparing an environmental assessment or environmental impact statement under 21 CFR 25.32(m). In accordance with regulations promulgated under the National Environmental Policy Act (40 CFR 1506.6(b)), we are placing the environmental document submitted with the subject petition on public display at the Division of Dockets Management (see **ADDRESSES**) so that interested persons may review the document. If we determine that the petitioners' claim of categorical exclusion is warranted and that neither an environmental assessment nor environmental impact statement is required, we will announce our determination in the **Federal Register** if this petition results in an amended regulation(s). If we determine that the claim of categorical exclusion is not warranted we will place the environmental assessment on public display at the Division of Dockets Management and provide notice in the **Federal Register** announcing its availability for review and comment.

Dated: May 13, 2016.

Dennis M. Keefe,

Director, Office of Food Additive Safety, Center for Food Additive Safety and Applied Nutrition.

[FR Doc. 2016–11866 Filed 5–19–16; 8:45 am]

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