

Availability and Summary of Documents Proposed for Incorporation by Reference

This document proposes to amend FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015. FAA Order 7400.9Z is publicly available as listed in the ADDRESSES section of this document. FAA Order 7400.9Z lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) Part 71 by modifying Class E En route domestic airspace extending upward from 1,200 feet above the surface in the vicinity of the Blue Mesa VOR/DME, Blue Mesa, CO. One small airspace area northwest, near Montrose, CO, and one small airspace area southeast, near Trinidad, CO, both excluded from the current boundary, would be added for the safety and management of IFR operations, specifically point-to-point, en route operations outside of the established airway structure, and Air Traffic Control vectoring services.

Class E airspace designations are published in paragraph 6006 of FAA Order 7400.9Z, dated August 6, 2015, and effective September 15, 2015, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, "Environmental Impacts: Policies and Procedures" prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

- 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

- 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015, is amended as follows:

Paragraph 6006 En Route Domestic Airspace Areas.

* * * * *

ANM CO E6 Blue Mesa, CO [Amended]

Blue Mesa VOR/DME, CO

(Lat. 38°27'08" N., long. 107°02'23" W.)

That airspace extending upward from 1,200 feet above the surface within an area bounded by Lat. 35°39'30" N., long. 107°25'27" W.; to Lat. 36°14'38" N., long. 107°40'25" W.; to Lat. 37°16'00" N., long. 108°22'00" W.; to Lat. 37°58'51" N., long. 108°22'29" W.; to Lat. 39°01'00" N., long. 107°47'00" W.; to Lat. 39°07'40" N., long. 107°13'47" W.; to Lat. 39°11'48" N., long. 106°29'16" W.; to Lat. 39°40'23" N., long. 103°29'02" W.; to Lat. 36°59'57" N., long. 104°18'04" W.; to Lat. 36°17'00" N., long. 104°14'00" W.; to Lat. 36°12'53" N., long. 104°56'21" W.; to Lat. 36°13'34" N., long. 105°54'42" W.; thence to the point of beginning.

Issued in Seattle, Washington, on July 29, 2016.

Tracey Johnson,

Manager, Operations Support Group, Western Service Center.

[FR Doc. 2016–18676 Filed 8–5–16; 8:45 am]

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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; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is reopening the comment period for the notice of filing that appeared in the **Federal Register** of May 20, 2016 (81 FR 31877). In the notice, we requested comments on a filed food additive petition (FAP 6B4815), submitted by the 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. We are taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is reopening the comment period on the notice of filing of a food additive petition published on May 20, 2016 (81 FR 31877). Submit either electronic or written comments by September 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-265), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740-3835, 240-402-1188.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of May 20, 2016 (81 FR 31877), FDA published a notice of filing of a food additive petition (FAP 6B4815) submitted by the 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, c/o Mr. Thomas Neltner, 1875 Connecticut Ave. NW., Suite 600, Washington, DC 20009. The notice invited comments on the petition. The petition proposes that we amend and/or revoke specified regulations to no longer provide for the food contact use of specified ortho-phthalates. Specifically, the petitioners request that we 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 from 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 21 CFR 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).

We have received a request for a 60-day extension of the comment period for the petition. The request conveyed concern that the 60-day comment period does not allow sufficient time to collect and provide data and information and develop a meaningful and thoughtful response to the assertions set forth in the petition.

FDA has considered the request; however, because the request was submitted too late to allow us to extend the comment period, we are, instead, reopening the comment period until September 19, 2016. We believe that reopening the comment period until that date allows adequate time for interested persons to submit comments without significantly delaying our review.

Dated: August 2, 2016.

Dennis M. Keefe,

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

[FR Doc. 2016-18720 Filed 8-5-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1105

[Docket No. FDA-2016-N-1555]

Refuse To Accept Procedures for Premarket Tobacco Product Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a proposed rule describing when FDA would refuse to accept a tobacco product submission (or application) because the application has not met a minimum threshold for acceptability for FDA review. Under the proposed rule, FDA would refuse to accept a tobacco product submission, for example, that is not in English, does not pertain to a tobacco product, or does not identify the