

§ 416.903b Evidence from statutorily excluded medical sources.

(a) *General.* We will not consider evidence from the following medical sources statutorily excluded under section 223(d)(5)(C) of the Social Security Act (Act), as amended, unless we find good cause under paragraph (b) of this section:

(1) Any medical source that has been convicted of a felony under section 208 or under section 1632 of the Act;

(2) Any medical source that has been excluded from participation in any Federal health care program under section 1128 of the Act; or

(3) Any medical source that has received a final decision imposing a civil monetary penalty or assessment, or both, for submitting false evidence under section 1129 of the Act.

(b) *Good cause.* We may find good cause to consider evidence from a statutorily excluded medical source under section 223(d)(5)(C) of the Act, as amended, if:

(1) The evidence from the medical source consists of evidence of treatment that occurred before the date the source was convicted of a felony under section 208 or under section 1632 of the Act;

(2) The evidence from the medical source consists of evidence of treatment that occurred during a period in which the source was not excluded from participation in any Federal health care program under section 1128 of the Act;

(3) The evidence from the medical source consists of evidence of treatment that occurred before the date the source received a final decision imposing a civil monetary penalty or assessment, or both, for submitting false evidence under section 1129 of the Act;

(4) The sole basis for the medical source's exclusion under section 223(d)(5)(C) of the Act, as amended, is that the source cannot participate in any Federal health care program under section 1128 of the Act, but the Office of Inspector General of the Department of Health and Human Services granted a waiver of the section 1128 exclusion; or

(5) The evidence is a laboratory finding about a physical impairment and there is no indication that the finding is unreliable.

(c) *Statutorily excluded medical sources' reporting requirements.* Statutorily excluded medical sources (as described in paragraph (a) of this section) must inform us in writing that they are excluded under section 223(d)(5)(C) of the Act, as amended, each time they submit evidence related to a claim for benefits under titles II or XVI of the Act. This reporting requirement applies to evidence that

statutorily excluded medical sources submit to us either directly or through a representative, claimant, or other individual or entity.

(1) Statutorily excluded medical sources must provide a written statement, which contains the following information:

(i) A heading stating: "WRITTEN STATEMENT REGARDING SECTION 223(d)(5)(C) OF THE SOCIAL SECURITY ACT—DO NOT REMOVE"

(ii) The name and title of the medical source;

(iii) The applicable excluding event(s) stated in paragraphs (a)(1)–(a)(3) of this section;

(iv) The date of the medical source's felony conviction under sections 208 or 1632 of the Act, if applicable;

(v) The date of the imposition of a civil monetary penalty or assessment, or both, for the submission of false evidence, under section 1129 of the Act, if applicable; and

(vi) The basis, effective date, anticipated length of the exclusion, and whether the Office of the Inspector General of the Department of Health and Human Services waived the exclusion, if the excluding event was the medical source's exclusion from participation in any Federal health care program under section 1128 of the Act.

(2) The written statement provided by an excluded medical source may not be removed by any individual or entity prior to submitting evidence to us.

(3) We may request that the excluded medical source provide us with additional information or clarify any information submitted that bears on the medical source's exclusion(s) under section 223(d)(5)(C) of the Act, as amended.

[FR Doc. 2016–13744 Filed 6–9–16; 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; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition; correction.

SUMMARY: The Food and Drug Administration (FDA or we) is correcting a notice entitled "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" that appeared in the **Federal Register** of May 20, 2016 (81 FR 31877). The document announced that 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 filed a petition proposing that we amend and/or revoke specified regulations to no longer provide for the food contact use of specified ortho-phthalates, but omitted two items. This document corrects that error.

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: In FR Doc. 2016–11866, appearing on page 31878 in the **Federal Register** of Friday, May 20, 2016, the following correction is made:

On page 31878, in the third column, under the heading "§ 175.300 *Resinous and Polymeric Coatings*," the

document is corrected to add “Butyl phthalyl butyl glycolate (CAS No. 85–70–1)” and “Ethyl phthalyl ethyl glycolate (CAS No. 84–72–0)” in alphabetical order.

Dated: June 7, 2016.

Dennis M. Keefe,

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

[FR Doc. 2016–13739 Filed 6–9–16; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2016–0169]

RIN 1625–AA08

Special Local Regulation; Cumberland River, Mile 190.0 to 191.5; Nashville, TN

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a special local regulation for all waters of the Cumberland River beginning at mile marker 190.0 and ending at mile marker 191.5 from 9 a.m. until noon on July 30, 2016. This proposed special regulation is necessary to provide safety for the participants in the “Music City SUP Race” marine event. This proposed rulemaking would prohibit persons and vessels from being in the special local regulated area unless authorized by the Captain of the Port Ohio Valley 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 June 27, 2016.

ADDRESSES: You may submit comments identified by docket number USCG–2016–0169 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 Petty Officer Ashley Schad, MSD Nashville, Nashville, TN, at 615–736–5421 or at Ashley.M.Schad@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations

DHS Department of Homeland Security
E.O. Executive order
FR Federal Register
NPRM Notice of proposed rulemaking
Pub. L. Public Law
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

On January 28, 2016, the Nashville Paddle Company notified the Coast Guard that it will be conducting a race from 9 a.m. to noon on July 30, 2016. The event will consist of at least 75 participants on various sized stand up paddle boards and kayaks on the Cumberland River. The Captain of the Port Ohio Valley (COTP) has determined that additional safety measures are necessary to protect participants, spectators, and waterway users during this event. Therefore, the Coast Guard proposes to establish a special local regulation on specified waters of the Cumberland River. This proposed regulation would be in effect from 9 a.m. until noon on July 30, 2016.

The purpose of this rulemaking is to ensure the safety of vessels and participants of the navigable waters before, during, and after the scheduled event. The Coast Guard proposes this rulemaking under authority in 33 U.S.C. 1233, which authorizes the Coast Guard to establish and define special local regulations under 33 CFR 100.

III. Discussion of Proposed Rule

The Captain of the Port Ohio Valley proposes to establish a special local regulated area from 9 a.m. to noon on July 30, 2016 for all waters of the Cumberland River beginning at mile marker 190.0 and ending at mile marker 191.5. The duration of the special local regulated area is intended to ensure the safety of vessels, participants, and these navigable waters before, during, and after the scheduled event. No vessel or person would be permitted to enter the special local regulated area without obtaining permission from the COTP or a designated representative. The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and executive orders (E.O.s) related to rulemaking. Below we summarize our analyses based on a number of these statutes and E.O.s, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

E.O.s 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if

regulation is necessary, to select regulatory approaches that maximize net benefits. E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This NPRM has not been designated a “significant regulatory action,” under E.O. 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget.

This regulatory action determination is based on the size, location, duration, and time-of-day of the special local regulated area.

This proposed special local regulation restricts transit on the Cumberland River from mile 190.0 to 191.5, for a short duration of 3 hours for one day; Broadcast Notices to Mariners and Local Notices to Mariners will also inform the community of this special local regulation so that they may plan accordingly for this short restriction on transit. Vessel traffic may request permission from the COTP Ohio Valley or a designated representative to enter the restricted area.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the special local regulated area may be small entities, for the reasons stated in section IV.A above this proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions