

the request in an electronic format and requesting an alternative format. Such request must include an explanation of why an alternative format is necessary. All submissions, including requests to submit the information in an alternative format, requests for exemptions, and all supporting information must be legible and in the English language. An exemption request must contain:

(1) The manufacturer's address and contact information;

(2) Identification of the tobacco product(s);

(3) A detailed explanation of the purpose of the modification;

(4) A detailed description of the modification, including a statement as to whether the modification involves adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive;

(5) A detailed explanation of why the modification is a minor modification of a tobacco product that can be sold under the Federal Food, Drug, and Cosmetic Act;

(6) A detailed explanation of why a report under section 905(j)(1) of the Federal Food, Drug, and Cosmetic Act intended to demonstrate substantial equivalence is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health;

(7) A certification (*i.e.*, a signed statement by a responsible official of the manufacturer) summarizing the supporting evidence and providing the rationale for the official's determination that the modification does not increase the tobacco product's appeal to or use by minors, toxicity, addictiveness, or abuse liability;

(8) Other information justifying an exemption; and

(9) An environmental assessment under part 25 of this chapter prepared in accordance with the requirements of § 25.40 of this chapter.

(c) *Exemption determination.* FDA will review the information submitted and determine whether to grant or deny an exemption request based on whether the criteria in section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act are met. FDA may request additional information if necessary to make a determination. FDA will consider the exemption request withdrawn if the information is not provided within the requested timeframe.

(d) *Rescission of an exemption.* FDA may rescind an exemption if it finds that the exemption is not appropriate for the protection of public health. In general, FDA will rescind an exemption only after notice and opportunity for a hearing under part 16 of this chapter is

provided. However, FDA may rescind an exemption prior to notice and opportunity for a hearing under part 16 of this chapter if the continuance of the exemption presents a serious risk to public health. In that case, FDA will provide the manufacturer an opportunity for a hearing as soon as possible after the rescission.

Subpart B—[Reserved]

Dated: June 29, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-16766 Filed 7-1-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

[Docket No. FDA-1978-N-0018] (formerly Docket No. 1978N-0038)

RIN 0910-AF43

Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use

Correction

In rule document 2011-14766 appearing on pages 35620-35665 in the issue of Friday, June 17, 2011, make the following correction:

§ 201.327 [Corrected]

In § 201.327, on page 35661, in the third column, § 201.327(i)(1)(ii)(A)(2) and (3) should read as follows:

(2) $V_i(\lambda) = 10^{0.094 * (298-\lambda)}$ ($298 < \lambda \leq 328$ nm)

(3) $V_i(\lambda) = 10^{0.015 * (140-\lambda)}$ ($328 < \lambda \leq 400$ nm)

[FR Doc. C1-2011-14766 Filed 7-1-11; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2011-0198]

RIN 1625-AA00

Safety Zone; Upper Mississippi River, Mile 856.0 to 855.0, Minneapolis, MN

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for

all waters of the Upper Mississippi River, from Mile 856.0 to 855.0, Minneapolis, Minnesota, and extending the entire width of the river. This safety zone is needed to protect participants and event personnel during the U.S. Wakeboard Nationals occurring on the Upper Mississippi River. Entry into this zone is prohibited unless specifically authorized by the Captain of the Port Upper Mississippi River or a designated representative during the period of enforcement.

DATES: This rule is effective from 8 a.m. on July 20, 2011 through 6 p.m. CDT on July 24, 2011.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG-2011-0198 and are available online by going to <http://www.regulations.gov>, inserting USCG-2011-0198 in the "Keyword" box, and then clicking "Search." They are also available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or e-mail Chief Petty Officer Bryan Klostermeyer, Sector Upper Mississippi River Response Department at telephone (314) 269-2566, e-mail Bryan.K.Klostermeyer@uscg.mil. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest."

Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not using the notice of proposed rulemaking (NPRM) process. The Coast Guard received notice of the U.S. Wakeboard Nationals event on May 11, 2011. This short notice did not allow the time needed to publish a NPRM and provide a comment period. Delaying this rule by publishing a NPRM would be impracticable because this rule is

needed to protect vessels and mariners from the safety hazards associated with the scheduled demonstration.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying this rule by providing a full 30 days notice would be impracticable because immediate action is needed to protect vessels and mariners from the safety hazards associated with a wakeboard competition.

Basis and Purpose

From July 20 through July 24, 2011, World Sports and Marketing will sponsor the U.S. Wakeboard Nationals between Mile 856.0 and 855.0 on the Upper Mississippi River in Minneapolis, Minnesota. This event presents safety hazards to the navigation of vessels between Mile 856.0 and 855.0, extending the entire width of the river.

Discussion of Rule

The Coast Guard is establishing a safety zone for all waters of the Upper Mississippi River, Mile 856.0 to 855.0, Minneapolis, Minnesota and extending the entire width of the river. Entry into this zone is prohibited to all vessels and persons except U.S. Wakeboard Nationals participants and those persons and vessels specifically authorized by the Captain of the Port Upper Mississippi River. This rule is effective from 8 a.m. on July 20, 2011 through 6 p.m. on July 24, 2011. This rule will be enforced daily from 9 a.m. until 5:30 p.m. on July 20 through 24, 2011. The Captain of the Port Upper Mississippi River will inform the public through broadcast notice to mariners of all safety zone requirements, changes, and enforcement periods.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This rule is not a “significant regulatory action” under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

Although this regulation will restrict access to this area, the effect of the rule

is not significant because this rule will be in effect for a limited time period and notifications to the marine community will be made through local notice to mariners.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. 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 rule will not have a significant economic impact on a substantial number of small entities. This rule will affect the following entities, some of which may be small entities: The owners or operators of vessels intending to transit the Upper Mississippi River, Mile 856.0 to 855.0 after 8 a.m. on July 20, 2011 through 6 p.m. CDT on July 24, 2011. This safety zone will not have a significant economic impact on a substantial number of small entities because this rule will only be in effect for a limited period of time.

If you are a small business entity and are significantly affected by this regulation, please contact Chief Petty Officer Bryan Klostermeyer, Sector Upper Mississippi River at (314) 269–2566.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency’s responsiveness to small businesses. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 or more in any one year. Though this rule will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a “significant energy action” under that Order because it is not a “significant regulatory action” under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies. This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023-01 and Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321-4370f), and have concluded this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2-1, paragraph 34(g), of the Instruction. This rule established a temporary safety zone. An environmental analysis checklist and a categorical exclusion determination will be available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05-1, 6.04-1, 6.04-6, and 160.5; Pub. L. 107-295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T11-0198 to read as follows:

§ 165.T11-0198 Safety Zone; Upper Mississippi River, Mile 856.0 to 855.0, Minneapolis, MN.

(a) *Location.* The following area is a safety zone: All waters of the Upper Mississippi River, Mile 856.0 to 855.0, Minneapolis, Minnesota, and extending the entire width of the waterway.

(b) *Effective date.* This rule is effective from 8 a.m. on July 20, 2011 through 6 p.m. on July 24, 2011.

(c) *Periods of Enforcement.* This rule will be enforced daily from 9 a.m. until 5:30 p.m. on July 20 through 24, 2011. The Captain of the Port Upper Mississippi River will inform the public of the enforcement periods and any safety zone changes through broadcast notice to mariners.

(d) *Regulations.* (1) In accordance with the general regulations in 33 CFR part 165, subpart C, entry into this zone is prohibited unless authorized by the Captain of the Port Upper Mississippi River or a designated representative.

(2) Persons or vessels requiring entry into or passage through the zone must request permission from the Captain of the Port Upper Mississippi River or a designated representative. The Captain of the Port Upper Mississippi River representative may be contacted at (314) 269-2332.

(3) All persons and vessels shall comply with the instructions of the Captain of the Port Upper Mississippi River or their designated representative. Designated Captain of the Port representatives include United States Coast Guard commissioned, warrant, and petty officers.

Dated: May 25, 2011.

S.L. Hudson,

Captain, U.S. Coast Guard, Captain of the Port Upper Mississippi River.

[FR Doc. 2011-16684 Filed 7-1-11; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R06-OAR-2007-0924; FRL-9323-7]

Approval and Promulgation of Air Quality Implementation Plans, State of Louisiana

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is finalizing approval of portions of State Implementation Plan (SIP) revisions for the State of Louisiana. The rule revisions, which cover the years 1996–2006, were submitted by the State of Louisiana, and include formatting changes, regulatory wording changes, substantive or content changes, and incorporation by reference (IBR) of Federal rules. The overall intended outcome will make the approved Louisiana SIP consistent with current Federal and State requirements. We are approving the revisions in accordance with 110 of the Clean Air Act (CAA or Act) and EPA’s regulations. **DATES:** This rule is effective August 4, 2011.

ADDRESSES: EPA has established a docket for this action under Docket No. EPA-R06-OAR-2007-0924. All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material will be publicly available only in hard copy.

Publicly available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy at the Air Planning Section (6PD-L), Environmental Protection Agency, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202-2733. The file will be made available by appointment for public inspection in the Region 6 FOIA Review Room between the hours of 8:30 a.m. and 4:30 p.m. weekdays except for legal holidays.

Contact the person listed in the **FOR FURTHER INFORMATION CONTACT** paragraph below to make an appointment. If possible, please make the appointment at least two working days in advance of your visit. There will be a fee of 15 cents per page for making photocopies of documents. On the day of the visit, please check in at the EPA Region 6 reception area at 1445 Ross Avenue, Suite 700, Dallas, Texas 75202-2733.