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 FDA will consider the exemption request withdrawn if the information is not provided within the requested timeframe.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]

BILLING CODE 4160–01–P

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]

BILLING CODE 1505–01–D

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