

swap dealers and major security-based swap participants become effective.

It is hereby further ordered, pursuant to section 36 of the Securities Exchange Act of 1934, that any person that meets the definition of eligible contract participant as set forth in section 1a(12) of the Commodity Exchange Act (as in effect on July 20, 2010) is exempt from the requirements of section 6(l) of the Securities Exchange Act of 1934 with respect to a transaction in a security-based swap until the effective date for the final rules further defining the term eligible contract participant, provided that such person effects such transaction with or for a person that also meets the definition of eligible contract participant as set forth in section 1a(12) of the Commodity Exchange Act (as in effect on July 20, 2010).

It is hereby further ordered, pursuant to section 36 of the Securities Exchange Act of 1934, that no contract entered into on or after July 16, 2011 shall be void or considered voidable by reason of section 29(b) of the Securities and Exchange Act of 1934 because any person that is a party to the contract violated a provision of the Securities Exchange Act of 1934 that was amended or added by subtitle B of the Wall Street Transparency and Accountability Act of 2010 and for which the Commission has taken the view that compliance will be triggered by registration of a person or by adoption of final rules by the Commission, or for which the Commission has provided an exception or exemptive relief herein, until such date as the Commission specifies.

By the Commission.

Dated: June 15, 2011.

Elizabeth M. Murphy,
Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 333

[Docket No. FDA-2011-D-0404]

Guidance for Industry on Topical Acne Drug Products for Over-the-Counter Human Use—Revision of Labeling and Classification of Benzoyl Peroxide as Safe and Effective; Small Entity Compliance Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; guidance.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for small business entities entitled “Topical Acne Drug Products for Over-the-Counter Human Use—Revision of Labeling and Classification of Benzoyl Peroxide as Safe and Effective.” This guidance is intended to help small businesses understand and comply with the requirements of the final rule that adds benzoyl peroxide as a generally recognized as safe and effective (GRASE) active ingredient in over-the-counter (OTC) topical acne drug products and provides new labeling requirements applicable to all OTC topical acne products marketed under the monograph (75 FR 9767, March 4, 2010) (final rule). The guidance describes the requirements of the final rule in plain language and provides answers to common questions on how to comply with the rule. This guidance was prepared in accordance with the Small Business Regulatory Fairness Act.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Arlene H. Solbeck, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5426, Silver Spring, MD 20993-0002, 301-796-2090.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for small business entities entitled “Topical Acne Drug Products for Over-the-Counter Human Use—Revision of Labeling and Classification of Benzoyl Peroxide as Safe and Effective; Small Entity Compliance Guide.” This guidance summarizes the March 4, 2010, final rule regarding topical acne drug products for OTC use

that makes the following changes to the OTC regulations:

- Adds benzoyl peroxide as a GRASE active ingredient in OTC topical acne drug products.
- Sets forth new warnings and a direction that must be included in labeling of OTC topical acne drug products that contain benzoyl peroxide.
- Revises labeling requirements for all OTC topical acne drug products to ensure consistency with the standardized drug facts formatting and requirements set forth in § 201.66 (21 CFR 201.66).

The guidance summarizes in table form the requirements for specific warnings and directions in the labeling that apply to all OTC acne drug products marketed under the monograph (*i.e.*, products that contain any of the active ingredients permitted under the OTC topical acne drug monograph, including benzoyl peroxide, resorcinol, resorcinol monoacetate, salicylic acid, and/or sulfur) (21 CFR part 333, subpart D)). The summaries include new warnings and a new “direction for use” required specifically for OTC topical acne products that contain benzoyl peroxide. The revised labeling requirements ensure that the labeling of OTC topical acne drug products is consistent with the standardized drug facts labeling content and format requirements in § 201.66.

FDA is issuing this small entity compliance guide as level 2 guidance consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency’s current thinking on the classification of benzoyl peroxide as GRASE in the OTC topical acne drug monograph, and revised labeling requirements for OTC topical acne products, as set forth in the final rule. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: June 16, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-15560 Filed 6-21-11; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG-2011-0540]

RIN 1625-AA08

Special Local Regulation for Marine Events; Temporary Change of dates for Recurring Marine Events in the Fifth Coast Guard District; Mill Creek, Hampton, VA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard will temporarily change the enforcement period of one special local regulation for recurring marine events in the Fifth Coast Guard District. This regulation applies a hydroplane speed boat race which was originally scheduled for August 12-14, 2011 will be on August 6-7, 2011. This regulation will restrict vessel traffic in portions of Mill Creek in Hampton, Virginia during the rescheduled event to protect mariners and the boating public from the potential hazards associated with hydroplane speed boats that will reach speeds in excess of 150 miles per hour.

DATES: This rule is effective from August 6, 2011, through August 15, 2011.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG-2011-0540 and are available online by going to <http://www.regulations.gov>, inserting USCG-2011-0540 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 LCDR Christopher A. O'Neal, Waterways Management Division Chief, Sector Hampton Roads, Coast Guard; telephone 757-668-5580, e-mail Christopher.A.ONeal@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 publishing a notice of proposed rulemaking (NPRM) with respect to this rule because delaying the effective date would be contrary to the public interest since immediate action is needed to ensure the safety of the event participants, patrol vessels, spectator craft and other vessels transiting the event area. The potential dangers posed by hydroplane speed boats, operating in speeds excess of 150 miles per hour, make special local regulations necessary. However, the Coast Guard will provide advance notifications to users of the effected waterways via marine information broadcasts, local notice to mariners, commercial radio stations and area newspapers. This regulation represents the re-scheduling of the event in order to de-conflict the event from another race that many competitors and a sponsor are involved in during the second weekend in August 2011 and to have the event take place close in time to the regularly scheduled dates of the event. In addition, publishing an NPRM is unnecessary because this event is an annual event which mariners should be aware of taking place, as it is noticed in the **Federal Register**. If mariners had concerns about this event taking place, they are on notice throughout the year of the event and can object to or comment about the event at any time. When the NPRM, including the table to § 100.501 listing all of the annual events, was made available for comment, there were no objections to this event.

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 the effective date would be contrary to the public interest since immediate action is needed to ensure the safety of the event participants, patrol vessels, spectator craft and other vessels transiting the event area. The potential dangers posed by hydroplane speed boats, operating in speeds excess of 150 miles per hour, make special local regulations necessary. However, the Coast Guard will provide advance notifications to users of the effected waterways via marine information broadcasts, local notice to mariners, commercial radio stations and area newspapers. This regulation represents the re-scheduling of the event in order to de-conflict the event from another race that many competitors and a sponsor are involved in during the second weekend in August 2011 and to have the event take place close in time to the regularly scheduled dates of the event. In addition, publishing an NPRM is unnecessary because this event is an annual event which mariners should be aware of taking place, as it is noticed in the **Federal Register**. If mariners had concerns about this event taking place, they are on notice throughout the year of the event and can object to or comment about the event at any time. When the NPRM, including the table to § 100.501 listing all of the annual events, was made available for comment, there were no objections to this event.

Background and Purpose

This event is annually held in August, scheduled to begin on the second Friday of August and anticipated to run through the Saturday and Sunday of that weekend. The regulation listing annual marine events within the Fifth Coast Guard District and their regulated dates is 33 CFR 100.501. A table to § 100.501 identifies marine events by Captain of the Port zone. This particular event, sponsored this year by the City of Hampton, Hampton Cup Regatta Racing Club and the Phoebus Civic Association, is listed at line No. 44.

This year, the Regatta was initially scheduled to take place on August 12-14, 2011. However, the event was rescheduled to take place one week earlier, on August 6-7, 2011. The date has changed due to participants and a sponsor being involved in another race during the second weekend in August. In order to deal with this conflict, the regatta date was pushed up one weekend in August 2011.