heading of this document and they may be accompanied by a supporting memorandum or brief. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 20 be amended as follows:

PART 20—PUBLIC INFORMATION

1. The authority citation for 21 CFR part 20 continues to read as follows:

Authority: 5 U.S.C. 552; 18 U.S.C. 1905; 19 U.S.C. 2531–2582; 21 U.S.C. 321–393, 1401–1403; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b–263n, 264, 265, 300u–300u–5, 300aa–1.

2. Amend section 20.108 as follows:

a. Revise paragraph (b);

b. Remove paragraph (c);

c. Redesignate paragraph (d) as paragraph (c);

d. Revise newly redesignated paragraph (c).

The revisions and redesignations read as follows:

§ 20.108 Agreements between the Food and Drug Administration and other departments, Agencies, and organizations.

* * * * *

(b) All written agreements and memoranda of understanding between FDA and any entity, including, but not limited to other departments, Agencies, and organizations will be made available through the Food and Drug Administration Web site at *http://www.fda.gov* once finalized.

(c) Agreements and understandings signed by officials of the Food and Drug Administration with respect to activities of the Office of Criminal Investigations are exempt from the requirements set forth in paragraph (b) of this section. Although such agreements and understandings will not be made available through the Food and Drug Administration Web site, these agreements will be available for disclosure in response to a request from the public after deletion of information that would disclose confidential investigative techniques or procedures, or information that would disclose guidelines for law enforcement investigations if such disclosure could reasonably be expected to risk circumvention of the law.

Dated: March 16, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–6969 Filed 3–22–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 202

[Docket No. FDA–2009–N–0582]

RIN 0910–AG27

Direct-to-Consumer Prescription Drug Advertisements; Presentation of the Major Statement in Television and Radio Advertisements in a Clear, Conspicuous, and Neutral Manner; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period on specific data.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period on specific data related to a proposed rule published in the **Federal Register** of March 29,, to establish standards that would be considered in determining whether the major statement in direct-to-consumer (DTC) television and radio advertisements relating to the side effects and contraindications of an advertised prescription drug intended for use by humans is presented in a clear, conspicuous, and neutral manner. In the **Federal Register** of January 27, 2012, FDA announced that it had added a document to the docket for the proposed rulemaking concerning a study entitled ''Experimental Evaluation of the Impact of Distraction on Consumer Understanding of Risk and Benefit Information in Direct-to-Consumer Prescription Drug Television Advertisements'' (Distraction Study) and the public was given until February 27, 2012, to comment on this study as it relates to the proposed standards. FDA is reopening the comment period for the rulemaking proceeding in response to a request for more time to submit comments to the Agency.

DATES: Submit either electronic or written comments on the Distraction Study report as it relates to the proposed standards by April 9, 2012.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2009–N–0582 and/or Regulatory Information Number (RIN) 0910–AG27, by any of the following methods.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *FAX:* 301–827–6870.
- *Mail/Hand delivery/Courier (For paper or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name, docket number, and RIN for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or 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:

For information concerning human drug products: Ernest S. Voyard, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 3276, Silver Spring, MD 20993–0002, 301–796–3832.

For information concerning human biological drug products: Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 29, 2010 (75 FR 15376), FDA published a proposed rule entitled ''Direct-to-Consumer Prescription Drug Advertisements; Presentation of the Major Statement in Television and Radio Advertisements in a Clear, Conspicuous, and Neutral Manner,'' to amend its regulations concerning DTC advertisements of prescription drugs. Specifically, the proposed rule would implement a new requirement of the

Federal Food, Drug, and Cosmetic Act (the FD&C Act), added by section 901(d)(3)(A) of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85) (FDAAA). This section requires that the major statement in DTC television or radio advertisements relating to the side effects and contraindications of an advertised prescription drug intended for use by humans be presented in a clear, conspicuous, and neutral manner, and directs FDA to publish regulations establishing the standards for determining whether a major statement meets these requirements. As directed by section 901(d)(3)(B) of FDAAA, the proposed rule described standards that the Agency would consider in determining whether the major statement is clear, conspicuous, and neutral, and it provided a 90-day period for public comment, which closed on June 28, 2010.

On January 27, 2012 (77 FR 4273), FDA reopened the comment period on this rulemaking until February 27, 2012, to allow an opportunity for interested parties to comment on FDA's analyses of the results of its study (see attachment in Docket No. FDA–2009–N–0582–0040) on the impact of distraction on consumer understanding of risk and benefit information in DTC prescription drug television advertisements (72 FR 47051, August 22, 2007) (Distraction Study) as it relates to the proposed standards. The Pharmaceutical Research and Manufacturers of America (PhRMA) submitted a letter dated February 20, 2012, requesting an additional 15 days for interested persons to comment. FDA believes that an additional 15 days to comment on the Distraction Study as it relates to the proposed standards is appropriate.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding the Distraction Study as it relates to the proposed standards. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document and label them ''ATTN: Distraction Study.'' The data and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 16, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–6948 Filed 3–22–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 100

[Docket No. USCG–2012–0073]

RIN 1625–AA08

Special Local Regulations; Ocean State Tall Ships Festival 2012, Narragansett Bay, RI

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish temporary special local regulations on the navigable waters of Narragansett Bay and Newport Harbor, Rhode Island, for the Ocean State Tall Ships Festival 2012. This action is necessary to provide for the safety of life and property on the navigable waters of Narragansett Bay and Newport Harbor, Rhode Island, during the Ocean State Tall Ships Festival on July 6–9, 2012. These temporary special local regulations would restrict vessel traffic in portions of Narragansett Bay and Newport Harbor, Rhode Island, unless authorized by the Captain of the Port (COTP) Sector Southeastern New England.

DATES: Comments and related material must be received by the Coast Guard on or before May 22, 2012. Requests for public meetings must be received by the Coast Guard on or before April 13, 2012.

ADDRESSES: You may submit comments identified by docket number USCG–2012–0073 using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov*.

(2) *Fax:* 202–493–2251.

(3) *Mail or Delivery:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. Deliveries accepted between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays. The telephone number is 202–366–9329. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for further instructions on submitting comments. To avoid duplication, please use only one of these three methods.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or email Mr. Edward G. LeBlanc, Waterways Management Division at Coast Guard Sector Southeastern New England, telephone 401–435–2351, email *Edward.G.LeBlanc@uscg.mil*. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2012–0073), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online (via *http://www.regulations.gov*) or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via *http://www.regulations.gov,* it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* type the docket number (USCG–2012–0073 in the ''SEARCH'' box and click ''SEARCH.'' Click on ''Submit a Comment'' on the line associated with this rulemaking.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to