reasonably foreseeable risks, adverse reactions, anticipated benefits, drug interactions, and any other relevant information required by FDA at the time of approval. For self-administered biological products, there shall be unit-of-use packaging and attached patient labeling containing this information. For biological products administered by health professionals, the patient labeling shall be available with the product to be provided to patients prior to administration of the biological product, if possible.

§ 601.62 Withdrawal procedures.

(a) For biological products approved under this subpart, FDA may withdraw approval, following a hearing as provided in part 15 of this chapter, as modified by this section, if:

(1) A postmarketing clinical study fails to verify clinical benefit;

(2) The applicant fails to perform the postmarketing study with due diligence;

(3) Use after marketing demonstrates that postmarketing restrictions are inadequate to assure safe use of the biological product;

(4) The applicant fails to adhere to the postmarketing restrictions applied at the time of approval under this subpart;

(5) The promotional materials are false or misleading; or

(6) Other evidence demonstrates that the biological product is not shown to be safe or effective under its conditions of use.

(b) *Notice of opportunity for a hearing.* The Director of the Center for Biologics Evaluation and Research (CBER) will give the applicant notice of an opportunity for a hearing on the CBER's proposal to withdraw the approval of an application approved under this subpart. The notice, which will ordinarily be a letter, will state generally the reasons for the action and the proposed grounds for the order.

(c) *Submission of data and information.* (1) If the applicant fails to file a written request for a hearing within 15 days of receipt of the notice, the applicant waives the opportunity for a hearing.

(2) If the applicant files a timely request for a hearing, the agency will publish a notice of hearing in the **Federal Register** in accordance with §§ 12.32(e) and 15.20 of this chapter.

(3) An applicant who requests a hearing under this section must, within 30 days of receipt of the notice of opportunity for a hearing, submit the data and information upon which the applicant intends to rely at the hearing.

(d) *Separation of function.* Separation of functions (as specified in § 10.55 of this chapter) will not apply at any point in withdrawal proceedings under this section.

(e) *Procedures for hearings.* Hearings held under this section will be conducted in accordance with the provisions of part 15 of this chapter, with the following modifications:

(1) An advisory committee duly constituted under part 14 of this chapter will be present at the hearing. The committee will be asked to review the issues involved and to provide advice and recommendations to the Commissioner of Food and Drugs.

(2) The presiding officer, the advisory committee members, up to three representatives of the applicant, and up to three representatives of CBER may question any person during or at the conclusion of the person's presentation. No other person attending the hearing may question a person making a presentation. The presiding officer may, as a matter of discretion, permit questions to be submitted to the presiding officer for response by a person making a presentation.

(f) *Judicial review.* The Commissioner of Food and Drugs' decision constitutes final agency action from which the applicant may petition for judicial review. Before requesting an order from a court for a stay of action pending review, an applicant must first submit a petition for a stay of action under § 10.35 of this chapter.

§ 601.63 Postmarketing safety reporting.

Biological products approved under this subpart are subject to the postmarketing recordkeeping and safety reporting applicable to all approved biological products.

§ 601.64 Promotional materials.

For biological products being considered for approval under this subpart, unless otherwise informed by the agency, applicants shall submit to the agency for consideration during the preapproval review period copies of all promotional materials, including promotional labeling as well as advertisements, intended for dissemination or publication within 120 days following marketing approval. After 120 days following marketing approval, unless otherwise informed by the agency, the applicant shall submit promotional materials at least 30 days prior to the intended time of initial dissemination of the labeling or initial publication of the advertisement.

§ 601.65 Termination of requirements.

If FDA determines after approval under this subpart that the requirements established in §§ 601.61(b), 601.62, and 601.63 are no longer necessary for the safe and effective use of a biological product, it will so notify the applicant. Ordinarily, for biological products approved under § 601.61, these requirements will no longer apply when FDA determines that the postmarketing study verifies and describes the biological product's clinical benefit. For biological products approved under § 601.61, the restrictions would no longer apply when FDA determines that safe use of the biological product can be assured through appropriate labeling. FDA also retains the discretion to remove specific postapproval requirements upon review of a petition submitted by the sponsor in accordance with § 10.30 of this chapter.

Dated: May 25, 1999.

Jane E. Henney,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 99–25377 Filed 10–4–99; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 20

46 CFR Part 5

[USCG–1998–3472]

RIN 2115–AF59

Rules of Practice, Procedure, and Evidence for Administrative Proceedings of the Coast Guard

AGENCY: Coast Guard, DOT.

ACTION: Reopening of comment period on interim rule.

SUMMARY: The Coast Guard is reopening the period for public comment on its interim rule, Rules of Practice, Procedure, and Evidence for Administrative Proceedings of the Coast Guard. Because of several requests for extension, the Coast Guard is reopening the period for 180 days.

DATES: Comments must reach the Coast Guard on or before April 3, 2000.

ADDRESSES: Please submit your comments and related material by any one of the following methods (but by only one, to avoid multiple listings in the public docket):

(1) By mail to the Docket Management Facility, [USCG–1998–3472], U.S. Department of Transportation, room PL–401, 400 Seventh Street SW., Washington, DC 20590–0001.

(2) By delivery to room PL–401 on the Plaza level of the Nassif Building, 400

Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(3) By fax to the Docket Management Facility at 202–493–2251.

(4) Electronically through the Web Site for the Docket Management System at http://dms.dot.gov.

FOR FURTHER INFORMATION CONTACT: For questions on the substance of the rulemaking, call George J. Jordan, Attorney-Adviser, Office of the Chief Administrative Law Judge, telephone 202–267–0006. For questions on viewing or submitting material to the docket, call Ms. Dorothy Walker, Chief of Dockets, Department of Transportation, telephone 202–366–9329.

SUPPLEMENTARY INFORMATION:

Request for Comments

The interim rule, published on May 24, 1999 [64 FR 28054], encouraged interested persons to participate in this rulemaking by submitting written data, views, or arguments by July 23, 1999. This request does the same, except that it invites their submitting them by April 3, 2000.

Persons submitting comments should include their names and addresses, identify this docket [USCG–1998–3472] and the specific section of the interim rule to which each comment applies, and give the reason for each comment. Please submit one copy of each comment and attachment in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing, to the DOT Docket Management Facility at the address under **ADDRESSES.** If you want acknowledgment of receipt of your comment, enclose a stamped, self-addressed postcard or envelope.

The Coast Guard will consider all comments received during the comment period. It may change this interim rule in view of them.

The Coast Guard plans no public meeting. Persons may request one by writing to the Docket Management Facility at the address under **ADDRESSES.** The request must identify this docket [USCG–1998–3472] and should include the reasons why an opportunity for oral presentations would be helpful to this rulemaking. If such an opportunity would help the rulemaking, the Coast Guard will hold a public meeting at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

The Coast Guard seeks to improve its adjudicative process. Improvement will also affect certain actions involving merchant mariners. First, the interim rule consolidates all Coast Guard adjudicative procedures to include the following: the suspension and revocation (S&R) of merchant mariners' licenses, certificates of registry, and documents and the procedures involving class II civil penalties. Second, the interim rule eliminates unnecessary procedures from S&R proceedings. The Coast Guard expects the interim rule to facilitate the efficient use of administrative resources relating to adjudication by the Coast Guard. It will save time, effort, and money for all parties who are or may become involved in actions of the Coast Guard.

Dated: September 27, 1999.

Robert S. Horowitz,

Acting Chief Counsel.

[FR Doc. 99–25865 Filed 10–4–99; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 175

[USCG–1999–6219]

Recreational Boating Safety—Federal Requirements for Wearing Personal Flotation Devices

AGENCY: Coast Guard, DOT.

ACTION: Notice; request for comments.

SUMMARY: The Coast Guard seeks (we seek) comments from interested people, groups, and businesses about the need for, and possible alternatives to, Federal requirements or incentives for people to wear lifejackets while engaged in a limited number of specific boating activities on the water. We will consider all comments and consult further with the National Boating Safety Advisory Council (NBSAC) to determine whether we should propose any Federal rules that would help to reduce the number of recreational boaters who drown in the circumstances identified by this notice and by the comments to it.

DATES: Comments and related material must reach the Docket Management Facility on or before April 3, 2000.

ADDRESSES: To make sure your comments and related material (referred to USCG–1999–6219) are not entered more than once in the docket, please submit them by only one of the following means:

(1) By mail to the Docket Management Facility, U.S. Department of Transportation, room PL–401, 400 Seventh Street SW., Washington, DC 20590–0001.

(2) By hand delivery to room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street S.W., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(3) By fax to the Docket Management Facility at 202–493–2251.

(4) Electronically through the Web Site for the Docket Management System at http://dms.dot.gov.

The Docket Management Facility maintains the public docket for this notice. Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at room PL–401 on the Plaza level of the Nassif Building, at the same address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at http://dms.dot.gov.

FOR FURTHER INFORMATION CONTACT: For questions on this notice, contact Carlton Perry, Project Manager, Office of Boating Safety, by telephone at 202–267–0979 or by e-mail at *cperry@comdt.uscg.mil.* For questions on viewing or submitting material to the docket, call Dorothy Walker, Chief, Dockets, Department of Transportation, telephone 202–366–9329.

You may obtain a copy of this notice by calling the U.S. Coast Guard Infoline at 1–800–368–5647, or read it on the Internet at the Web Site for the Office of Boating Safety at http://www.uscgboating.org or at http://dms.dot.gov.

SUPPLEMENTARY INFORMATION:

Regulatory History

On September 25, 1997, we published in the **Federal Register** a notice of request for comments [62 FR 50280]. That notice, with the title ''Recreational Boating Safety—Federal Requirements for Wearing Personal Flotation Devices'', under docket number CGD 97–059, set the closing date for comments for February 2, 1998. On March 20, 1998, we published a second notice [63 FR 13586]. That notice, with the same title and under the same docket number, reopened the comment period until May 29, 1998.

Background and Purpose

A number of responses to the initial notice commented that the best way to prevent drowning was to keep people from falling into the water in the first place. Our review of data on recreational boating accidents indicates