

Administrator). Class I substances include CFC's, halons, carbon tetrachloride, methyl chloroform, methyl bromide, and other chemicals not relevant to this document (see 40 CFR part 82, appendix A to subpart A). Class II substances include hydrochlorofluorocarbons (HCFC's) (see 40 CFR part 82, appendix B to subpart A).

II. Petition Received by FDA

BIPI submitted a petition under § 2.125(f) and 21 CFR part 10 requesting an addition to the list of CFC uses considered essential. The petition is on file under the docket number appearing in the heading of this document and may be seen in the Dockets Management Branch (address above). The petition requested that metered-dose albuterol sulfate and ipratropium bromide in combination for oral inhalation be included in § 2.125(e) as an essential use of CFC's. The petition contained a discussion supporting the position that there are no technically feasible alternatives to the use of CFC's in the product. The petition included information showing that no alternative delivery systems (e.g., the dry powder inhaler) or other substitute propellants (e.g., compressed gases) can dispense the drug for effective inhalation therapy as safely and uniformly, in all situations, as CFC propellants. Also, the petition stated that the product provides a substantial health benefit that would not be obtainable without the use of CFC's. In this regard, the petition contained information to support the use of this product as a combination bronchodilator. The petition asserted that metered-dose albuterol sulfate and ipratropium bromide in combination potentially reduces the amount of CFC's released into the atmosphere attributable to patients using one MDI for the combination product, rather than two MDI's, one for each of the two active ingredients.

III. FDA'S Review of the Petition

The agency has tentatively decided that for some chronic obstructive pulmonary disease patients, the use of metered-dose albuterol sulfate and ipratropium bromide in combination provides a special benefit that would be unavailable without the use of CFC's, and that the use of the drugs in combination has the potential to reduce the amount of CFC's released into the atmosphere. In this regard, FDA notes that albuterol sulfate and ipratropium bromide are currently listed separately (i.e., not in combination) in § 2.125(e) as essential uses of CFC's. Based on the evidence currently before it, FDA also

agrees that the use of a metered-dose delivery system for this product does not involve a significant release of CFC's into the atmosphere. Therefore, FDA is proposing to amend § 2.125(e) to include metered-dose albuterol sulfate and ipratropium bromide in combination for oral inhalation in the list of essential uses of CFC propellants.

A copy of this document has been provided to the Administrator.

IV. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the agency is not aware of any adverse impact of this proposed rule will have on any small entities, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

V. Opportunity for Comments

Interested persons may, on or before November 16, 1995, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 2

Administrative practice and procedure, Cosmetics, Devices, Drugs, Foods.

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 2 be amended as follows:

PART 2—GENERAL ADMINISTRATIVE RULINGS AND DECISIONS

1. The authority citation for 21 CFR part 2 continues to read as follows:

Authority: Secs. 201, 301, 305, 402, 408, 409, 501, 502, 505, 507, 512, 601, 701, 702, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 335, 342, 346a, 348, 351, 352, 355, 357, 360b, 361, 371, 372, 374); 15 U.S.C. 402, 409.

2. Section 2.125 is amended by adding new paragraph (e)(14) to read as follows:

§ 2.125 Use of chlorofluorocarbon propellants in self-pressurized containers.

* * * * *

(e) * * *

(14) Metered-dose ipratropium bromide and albuterol sulfate, in combination, administered by oral inhalation for human use.

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Dated: October 10, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95-25619 Filed 10-16-95; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 84

[CGD 95-037]

Adequacy of Barge and Tug Navigation Lights

AGENCY: Coast Guard, DOT.

ACTION: Notice of meeting; request for comments.

SUMMARY: The Coast Guard will conduct a public meeting to obtain information from members of the regulated community and the general public on lighting requirements for towing vessels and vessels being towed under Navigation Rule 24. This action is in response to concerns expressed by the marine community, both commercial and recreational, that current lighting requirements are not adequate.

DATES: The meeting will be held on November 11, 1995, from 9:15 a.m. to 12 noon. Written material must be received not later than December 18, 1995.

ADDRESSES: The meeting will be held at the Holiday Inn Downtown/Convention Center, 811 North Ninth Street, St. Louis, MO 63101. Written comments

may be mailed to the Executive Secretary, Marine Safety Council (G-LRA), U.S. Coast Guard, 2100 Second Street SW., Washington, DC 20593-0001, or may be delivered to room 3406 at the same address between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments will become part of this docket and will be available for inspection or copying at room 3406, Coast Guard Headquarters, between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Ms. Margie G. Hegy, Vessel Traffic Services Division (G-NVT), U.S. Coast Guard, 2100 Second Street SW., Washington, DC 20593, telephone (202) 267-0415.

SUPPLEMENTARY INFORMATION: The Inland Navigation Rules (Navigation Rules) are set forth in 33 U.S.C. 2001 *et seq.* Lighting requirements for towing vessels and vessels under tow are contained in Rule 24, 33 U.S.C. 2024. Under 33 U.S.C. 2701, the Secretary of Transportation may issue regulations to implement and interpret the Navigation Rules. The Secretary is also directed to establish technical annexes. The technical annex for lighting requirements is contained in 33 CFR Part 84. This annex specifies placement requirements for lights, including placement of lights on towing vessels and vessels under tow.

Safety concerns associated with towing operations and small craft traffic have been raised in recent years in several publications, including the American Boat and Yacht Council Newsletter, U.S. Coast Guard Boating Safety Circulars, America's Inland and Coastal Tug and Barge Operators pamphlet "Life Lines", and various yachting magazines. The safety aspects of barge lighting were discussed at the May 1994 meeting of the National Boating Safety Advisory Council (NBSAC). At its November 1994 meeting, the Navigation Safety Advisory Council (NAVSAC) was asked to consider whether current tug and tow lighting requirements under Navigation Rule 24 are adequate.

After considerable discussion, NAVSAC concluded that additional information was needed to determine whether there was an actual problem, and, if so, possible solutions. The Council unanimously passed a resolution requesting that the Coast Guard solicit public comments on whether towing vessels and vessels being towed are sufficiently lighted while underway.

On May 9, 1995, the Coast Guard published a Request for Comments in

the Federal Register (60 FR 24598). The Coast Guard received 64 comments from offshore commercial operators, inland tug and tow operators, and recreational boaters. The comments were mixed on whether the lighting required on barges is adequate, but all three user groups cited the following key problem areas:

(1) Lack of understanding of the Rules of the Road;

(2) Flaws in the Rules of the Road (i.e. lighting for sail vessels, vessels under oar, and vessels being towed are the same); and

(3) Poor equipment (i.e. dim lights, positioning of lights, use of household bulbs for navigation lights, use of portable lights which are not required to meet vertical sector requirements, and tug lights obscured by barges).

The Coast Guard is interested in receiving your comments, especially on the three key problem areas cited by previous comments. Comments should clearly describe your experiences and any problems associated with barge lighting and, if possible, provide potential solutions. The Coast Guard is particularly interested in recommendations that would not require amendment of the Navigation Rules and that conform with the International Rules. In adopting the International Regulations for Prevention of Collisions at Sea, 1972 (72 COLREGS), the United States not only agreed that its vessels would abide by those regulations when in international waters, but also that any special rules adopted by the United States for use on waterways connected with the high seas and navigable by seagoing vessels would "conform as closely as possible to these rules" (72 COLREGS, Rule 1).

To assist NAVSAC in their review of this issue, the public meeting will be part of the Council's November meeting in St. Louis, MO. All written and oral comments, including those received in response to the previously published notice, will be considered by the Coast Guard and NAVSAC.

Attendance is open to the public. With advance notice, and as time permits, members of the public may make oral presentations during the meeting. Persons wishing to make oral presentations should notify the person listed above under **FOR FURTHER INFORMATION CONTACT** no later than the day before the meeting. Written material may be submitted prior to, during, or after the meeting.

Dated: October 11, 1995.

Rudy K. Peschel,
Rear Admiral, U.S. Coast Guard Chief, Office of Navigation, Safety and Waterway Services.
[FR Doc. 95-25714 Filed 10-16-95; 8:45 am]

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33 CFR Part 187

[CGD 89-050]

RIN 2115-AD35

Vessel Identification System

AGENCY: Coast Guard, DOT.

ACTION: Proposed rule; reopening of comment period and notice of public hearings.

SUMMARY: On April 25, 1995, the Coast Guard published an interim final rule (IFR) regarding the establishment of a vessel identification system. The IFR provided a 90-day comment period that closed on July 24, 1995. The Coast Guard is reopening the comment period for an additional 75 days.

DATES: Comments must be received on or before December 31, 1995. Two public hearings will be held on November 13 and December 11, 1995, from 9 a.m. to 5 p.m. on each of those days.

ADDRESSES: Comments may be mailed to the Executive Secretary, Marine Safety Council, (G-LRA-2/3406) [CGD 89-050], U.S. Coast Guard Headquarters, 2100 Second Street SW., Washington, DC 20593-0001, or may be delivered to room 3406 at the above address between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (202) 267-1477. The Executive Secretary maintains the public docket for this rulemaking. Comments will become part of this docket and will be available for inspection or copying at room 3406, U.S. Coast Guard headquarters.

The hearings will be held at U.S. Coast Guard Headquarters, room 2415, 2100 Second Street SW., Washington, DC 20593-0001.

FOR FURTHER INFORMATION CONTACT: LCDR Richard Ferraro, Office of Marine Safety, Security and Environmental Protection, Information Resources Division (G-MIR), (202) 267-0386.

SUPPLEMENTARY INFORMATION:

Request for Comments

The Coast Guard encourages interested persons to participate in this rulemaking by submitting written data, views or arguments. Persons submitting comments should include their names and addresses, identifying this