not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 is revised to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9C, Airspace Designations and Reporting Points, dated August 17, 1995, and effective September 16, 1995, is amended as follows:

Paragraph 6002 Class E airspace areas designated as a surface area for an airport.

* * * * *

AWP CA E2 Mammoth Lakes, CA [New]

Mammoth Lakes Airport, CA
(Lat. 37°37′26″ N, long. 118°50′19″ W)

Within a 4.1-mile radius of the Mammoth Lakes Airport and within 1.8 miles each side of the 099° bearing from the Mammoth Lakes Airport, extending from the 4.1-mile radius to 5.6 miles southwest of the Mammoth Lakes Airport. This Class E airspace area is effective during the specific dates and times established in advancd by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AWP CA E5 Mammoth Lakes, CA [New]

Mammoth Lakes Airport, CA
(Lat. 37°37′26″ N, long. 118°50′19″ W)

That airspace extending upward from 700 feet above the surface within a 4.1-mile radius of the Mammoth Lakes Airport and within 1.8 miles each side of the 099° bearing from the Mammoth Lakes Airport, extending from the 4.1-mile radius to 5.6 miles southwest of the Mammoth Lakes Airport. That airspace extending upward from 1,200 feet above the surface within the area bounded by a line beginning a lat. 37°49′00″ N, long. 118°58′00″ W; to lat. 37°49′00″ N, long. 119°13′00″ W; to lat. 38°10′00″ N, long. 119°13′00″ W; to lat. 38°10′00″ N, long. 118°34′00″ W; thence to the point of beginning.

* * * * *

Issued in Los Angeles, California, on October 2, 1995.

Richard R. Lien,

Manager, Air Traffic Division, Western-Pacific Region.

[FR Doc. 95–25675 Filed 10–16–95; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 2

[Docket No. 92P–0403]

Chlorofluorocarbon Propellants in Self-Pressurized Containers; Addition to List of Essential Uses

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to grant the petition of Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI), to add metered-dose albuterol sulfate and ipratropium bromide in combination for oral inhalation to the list of products containing a chlorofluorocarbon (CFC) propellant for an essential use. Essential use products are exempt from FDA's ban on the use of CFC propellants in FDA-regulated products and the Environmental Protection Agency's (EPA's) ban on the use of CFC's in pressurized dispensers. This document proposes to amend FDA's regulations governing use of CFC's to include metered-dose albuterol sulfate and ipratropium bromide in combination for oral inhalation as an essential use.

DATES: Written comments by November 16, 1995.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD–362), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1049.

SUPPLEMENTARY INFORMATION:

I. Background

Under § 2.125 (21 CFR 2.125), any food, drug, device, or cosmetic in a self-pressurized container that contains a CFC propellant for a nonessential use is adulterated or misbranded, or both, under the Federal Food, Drug, and Cosmetic Act. This prohibition is based on scientific research indicating that CFC's may reduce the amount of ozone in the stratosphere and thereby increase the amount of ultraviolet radiation reaching the earth. An increase in ultraviolet radiation may increase the incidence of skin cancer, change the climate, and produce other adverse effects of unknown magnitude on humans, animals, and plants. Section 2.125(d) exempts from the adulteration and misbranding provisions of § 2.125(c) certain products containing CFC propellants that FDA determines provide unique health benefits that would not be available without the use of a CFC. These products are referred to in the regulation as essential uses of CFC's and are listed in § 2.125(e).

Under § 2.125(f), any person may petition the agency to request additions to the list of uses considered essential. To demonstrate that the use of a CFC is essential, the petition must be supported by an adequate showing that: (1) There are no technically feasible alternatives to the use of a CFC in the product; (2) the product provides a substantial health, environmental, or other public benefit unobtainable without the use of the CFC; and (3) the use does not involve a significant release of CFC's into the atmosphere or, if it does, the release is warranted by the consequence if the use were not permitted.

EPA regulations implementing provisions of the Clean Air Act contain a general ban on the use of CFC's in pressurized dispensers, such as metered-dose inhalers (MDI's) (40 CFR 82.64(c) and 82.66(d)). These regulations exempt from the general ban ''medical devices'' that FDA considers essential and that are listed in § 2.125(e). Section 601(8) of the Clean Air Act (42 U.S.C. 7671(8)) defines ''medical device'' as any device (as defined in the Federal Food, Drug, and Cosmetic Act), diagnostic product, drug (as defined in the Federal Food, Drug, and Cosmetic Act), and drug delivery system, if such device, product, drug, or drug delivery system uses a class I or class II ozone-depleting substance for which no safe and effective alternative has been developed (and where necessary, approved by the Commissioner of Food and Drugs (the Commissioner)); and if such device, product, drug, or drug delivery system has, after notice and opportunity for public comment, been approved and determined to be essential by the Commissioner in consultation with the Administrator of EPA (the

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.

* * * * *

Dated: October 10, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

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

BILLING CODE 4160–01–F

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