Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 101

Extension of Port Limits of Columbus, Ohio

AGENCY: Customs Service, Department of the Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document proposes to amend the Customs Regulations pertaining to the field organization of Customs by extending the geographical limits of the port of Columbus, Ohio, to include Rickenbacker Airport which is currently operating as a user fee airport. The boundary expansion of the Columbus port is proposed because enough business within the port has shifted to Rickenbacker Airport to make it worthwhile for the Customs Service to plan to relocate its port offices there. If the boundaries of the port are extended as proposed, the Customs Regulations would also be amended to remove Rickenbacker Airport's designation as a user fee airport. This proposed change is being made as part of Customs continuing program to obtain more efficient use of its personnel, facilities, and resources and to provide better service to carriers, importers, and the general public.

DATES: Comments must be received on or before April 30, 1996.

ADDRESSES: Written comments (preferably in triplicate) may be submitted to the Regulations Branch, Office of Regulations and Rulings, U. S. Customs Service, 1301 Constitution Avenue NW., Washington, D.C. 20229. Comments submitted may be inspected at the Regulations Branch, Office of Regulations and Rulings, 1099 14th Street NW., Suite 4000, Washington, D.C. on regular business days between the hours of 9:00 a.m. and 4:30 p.m.

FOR FURTHER INFORMATION CONTACT: Harry Denning, Office of Field Operations, (202) 927–0196.

SUPPLEMENTARY INFORMATION:

Background

As part of a continuing program to obtain more efficient use of its personnel, facilities, and resources, and to provide better service to carriers, importers, and the general public, Customs proposes to amend § 101.3, Customs Regulations (19 CFR 101.3) by extending the geographical limits of the port of Columbus, Ohio, to include the territory encompassing Rickenbacker Airport. Rickenbacker Airport is currently a user fee airport. Much business has shifted within the port to Rickenbacker Airport to make it worthwhile for Customs to include it within the Columbus port boundaries. Customs even plans to relocate its offices to Rickenbacker Airport. If the boundaries of the port of Columbus are extended as proposed, the Customs Regulations would also be amended to remove Rickenbacker Airport from the list of user fee airports in § 122.15, Customs Regulations. If the proposal is adopted, Customs will use existing staffing to service the expanded area of the port of Columbus, Ohio.

Current Port Limits of Columbus

The current port limits of the port of Columbus, Ohio were established in Treasury Decision (T.D.) 82–9, effective February 11, 1982. The current port limits of the port of Columbus include all of the territory within the corporate limits of Columbus, Ohio, all of the territory completely surrounded by the city of Columbus, and all of the territory enclosed by Interstate Highway 270 (outer belt), which completely surrounds the city.

Proposed Extension of Port

As proposed, the expanded port limits of Columbus, Ohio, would encompass the port limits set forth in T.D. 82–9 as well as the following territory:

Beginning at the intersection of Rohr and Lockbourne Roads, then proceeding southerly along Lockbourne Road to Commerce Street, thence easterly along Commerce Street to its intersection with the N & W railroad tracks, then southerly along the N & W railroad tracks to the Franklin-Pickaway County line, thence easterly along the Franklin-Pickaway County line to its intersection with Pontius Road, then northerly along Pontius Road to its intersection with Rohr Road, thence westerly along Rohr Road to its intersection with Lockbourne Road, the point of beginning, all within the County of Franklin, State of Ohio.

If the proposed extension of the port of Columbus is adopted, the limits in the port column adjacent to the listing of Columbus in the list of Customs ports of entry in 19 CFR 101.3 and the list of user fee airports in 19 CFR 122.15 will be amended accordingly.

Comments

Prior to adoption of this proposal, consideration will be given to written comments timely submitted to Customs. Submitted comments will be available for public inspection in accordance with the Freedom of Information Act (5 U.S.C. 552), section 1.4, Treasury Department Regulations (31 CFR 1.4), and section 103.11(b), Customs Regulations (19 CFR 103.11(b)), on regular business days between the hours of 9:00 a.m. and 4:30 p.m. at the Regulations Branch, Office of Regulations and Rulings, 1099 14th Street NW., Suite 4000, Washington, D.C.

Authority

This change is proposed under the authority of 5 U.S.C. 301 and 19 U.S.C. 2, 66, and 1624.

The Regulatory Flexibility Act and Executive Order 12866

Customs routinely establishes, expands, and consolidates Customs ports of entry throughout the United States to accommodate the volume of Customs-related activity in various parts of the country. Thus, although this document is being issued with notice for public comment, because it relates to agency management and organization, it is not subject to the notice and public procedure requirements of 5 U.S.C. 553. Accordingly, this document is not subject to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Agency organization matters such as this proposed port extension are exempt from consideration under Executive Order 12866.

Drafting Information: The principal author of this document was Janet L. Johnson, Regulations Branch. However, personnel

from other offices participated in its development.

George J. Weise,

Commissioner of Customs.

Approved: January 31, 1996.

Dennis M. O'Connell,

Acting Deputy Assistant Secretary of the Treasury.

[FR Doc. 96–4798 Filed 2–29–96; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 2

[Docket No. 95P–0088]

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 Bryan Corp. (Bryan) to add sterile aerosol talc 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 sterile aerosol talc as an essential use.

DATES: Written comments by April 1, 1996.

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

FOR FURTHER INFORMATION CONTACT: Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD–7), 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 and/or misbranded 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 (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

Bryan 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 sterile aerosol talc 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. It included information showing that no alternative delivery systems (e.g., the pneumatic atomizer) can assure consistent sterility. The petition also stated that Bryan is unaware of any appropriate substitute propellants (e.g., compressed gases). 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 in the treatment of malignant pleural effusions, a condition in which fluid accumulates in the space between the outside surface of the lung and the inside surface of the chest wall (pleural cavity) as a result of involvement by an underlying cancer. The petition also provided information indicating that use of the product would involve a limited release of CFC's into the atmosphere and the release is warranted by the health benefits of the product.

III. FDA'S Review of the Petition

The agency has tentatively decided that for many patients suffering from malignant pleural effusions, the use of sterile aerosol talc provides a special benefit that would be unavailable without the use of CFC's. Based on the evidence currently before it, FDA also agrees that the use of CFC's 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 sterile aerosol talc administered intrapleurally by thoracoscopy for human use 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