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]

BILLING CODE 4820–02–P

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

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 Public Comment

Interested persons may, on or before April 1, 1996, 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)(15) to read as follows:

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

* * * * *

(e) * * *

(15) Sterile aerosol talc administered intrapleurally by thoracoscopy for human use.

* * * * *

Dated: February 22, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–4714 Filed 2–29–96; 8:45 am]

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 324

[DFAS Regulation 5400.11–R]

Defense Finance and Accounting Service Privacy Act Program

AGENCY: Defense Finance and Accounting Service, DOD.

ACTION: Proposed rule.

SUMMARY: This proposed rule establishes the Defense Finance and Accounting Service (DFAS) Privacy Act Program. DFAS was established to provide finance and accounting services for the DoD Components and other Federal activities, as designated by the Comptroller, DoD.

The Defense Finance and Accounting Service was activated on January 15, 1991, to improve the overall effectiveness of DoD financial management through the consolidation, standardization and integration of finance and accounting systems, procedures and operations. DFAS is also responsible for identifying and implementing finance and accounting requirements, systems and functions for appropriated and non-appropriated funds, as well as working capital, revolving funds and trust fund activities--including security assistance.

DATES: Comments must be received by April 30, 1996, to be considered by the agency.

ADDRESSES: Send comments to the Defense Finance and Accounting Service, 1931 Jefferson Davis Highway, Room 416, Arlington, VA 22240–5291.

FOR FURTHER INFORMATION CONTACT: Ms. Genevieve Turney (703) 607–5165 or DSN 327–5165.

SUPPLEMENTARY INFORMATION: Executive Order 12866. The Director, Administration and Management, Office of the Secretary of Defense has determined that this Privacy Act rule for the Department of Defense does not constitute 'significant regulatory action'. Analysis of the rule indicates that it does not have an annual effect on the economy of $100 million or more; does not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; does not materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; does not raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866 (1993).

Regulatory Flexibility Act of 1980. The Director, Administration and Management, Office of the Secretary of Defense certifies that this Privacy Act rule for the Department of Defense does not have significant economic impact on a substantial number of small entities because it is concerned only with the administration of Privacy Act systems of records within the Department of Defense.

Paperwork Reduction Act. The Director, Administration and Management, Office of the Secretary of Defense certifies that this Privacy Act rule for the Department of Defense imposes no information requirements beyond the Department of Defense and that the information collected within the Department of Defense is necessary and consistent with 5 U.S.C. 552a, known as the Privacy Act of 1974.

This proposed rule establishes the Defense Finance and Accounting Service (DFAS) Privacy Act Program. DFAS was established to provide finance and accounting services for the DoD Components and other Federal activities, as designated by the Comptroller, DoD.

List of subjects in 32 CFR part 324

Privacy.

Accordingly, 32 CFR part 324 is added to read as follows:

PART 324–DFAS PRIVACY ACT PROGRAM

Subpart A–General Information

Subpart B–Systems of Records