Authority: 12 U.S.C. 4001 *et seq.*

2. In Appendix A to part 229, under the heading ''SECOND FEDERAL RESERVE DISTRICT,'' the numbers appearing directly under the subheading ''*Jericho Office*'' are transferred in numerical order under the subheading ''*East Rutherford Office*'', and the subheading ''*Jericho Office*'' is removed.

3. In Appendix B to part 229, the entry for ''*East Rutherford*'' is removed.

By order of the Board of Governors of the Federal Reserve System, May 15, 1996.

William W. Wiles,

Secretary of the Board.

[FR Doc. 96–12683 Filed 5–20–96; 8:45 am]

BILLING CODE 6210–01–P

RAILROAD RETIREMENT BOARD

20 CFR Part 200

RIN 3220–AB19

Availability of Information to Public

AGENCY: Railroad Retirement Board.

ACTION: Final rule.

SUMMARY: The Railroad Retirement Board (Board) hereby amends its regulations establishing fees to be assessed in connection with the search for records and provision of documents by the Board. The revision will eliminate the exemption from charge for the first 100 pages of reproduction and the first two hours of search time for requesters of documents who are not included within the specific categories provided in the regulations.

EFFECTIVE DATE: May 21, 1996.

ADDRESSES: Secretary to the Board, Railroad Retirement Board, 844 Rush Street, Chicago, Illinois 60611.

FOR FURTHER INFORMATION CONTACT: Michael C. Litt, Bureau of Law, Railroad Retirement Board, 844 Rush Street, Chicago, Illinois 60611, (312) 751–4929, TDD (312) 751–4701.

SUPPLEMENTARY INFORMATION: Section 200.4(g)(2)(v) of the Board's regulations provides for fees to be assessed in connection with the production of documents for ''All other requesters'', i.e. those requesters who do not fall within other categories provided for in the regulation. Those other categories include requests by commercial users, by educational and non-commercial scientific institutions, by representatives of the news media, and by subjects of records in Privacy Act Systems of Records. Currently § 200.4(g)(2)(v) provides that the Board does not charge ''other requesters'' for the first 100 pages of reproduction and the first two hours of search time.

The Board is authorized to charge for such costs of reproduction and search time by section 12(d) of the Railroad Unemployment Insurance Act (45 U.S.C. 362(d)) which provides, in pertinent part, that:

> * * * the Board may furnish such information to any person or organization upon payment by such person or organization to the Board of the cost incurred by the Board by reason thereof; and the amounts so paid to the Board shall be credited to the railroad unemployment insurance administration fund established pursuant to section 11(a) of this Act.

This provision is incorporated into the Railroad Retirement Act by section 7(b)(3) of that Act (45 U.S.C. 231f(b)(3)).

The Board has been receiving an increasing number of genealogical requests (almost 700 for the first six months of 1995 compared with about 450 for the same period in 1994) with a current estimated cost per request of $16.00. The Board has determined that it is more equitable that the costs for provision of this information be borne by the individuals who need the information, rather than the railroad industry as a whole. Accordingly, the Board proposes to eliminate the exemption from charge for the first 100 pages of reproduction and the first two hours of search time for requesters covered by § 200.4(g)(2)(v).

This rule was published as a proposed rule on January 18, 1996, inviting comments on or before March 18, 1996 (61 FR 1252). No comments were received.

The Board, with the concurrence of the Office of Management and Budget, has determined that this is not a significant regulatory action for purposes of Executive Order 12866. Therefore, no regulatory impact analysis is required. There are no information collections associated with this rule.

List of Subjects in 20 CFR Part 200

Railroad employees, Railroad retirement, Railroad unemployment insurance.

For the reasons set out in the preamble, title 20, chapter II, part 200 of the Code of Federal Regulations is amended as follows:

PART 200—GENERAL ADMINISTRATION

1. The authority citation for part 200 continues to read as follows:

Authority: 45 U.S.C. 231f(b)(5) and 45 U.S.C. 362; § 200.4 also issued under 5 U.S.C. 552; § 200.5 also issued under 5 U.S.C. 552a; § 200.6 also issued under 5 U.S.C. 552b; and § 200.7 also issued under 31 U.S.C. 3717.

2. Section 200.4 is amended by revising paragraph (g)(2)(v) to read as follows:

§ 200.4 Availability of information to public.

* * * * *

(g) * * *

(2) * * *

(v) *All other requesters.* For requesters who do not fall within the purview of paragraphs (g)(2) (i), (ii), (iii), or (iv) of this section, the RRB will charge the full direct cost of searching for and reproducing records that are responsive to the request. The RRB will not charge for such costs to be assessed if the total is less than $10.00. If the total is $10.00 or more, the RRB may waive the charge or reduce it if it determines that disclosure of the information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester.

* * * * *

Dated: May 7, 1996.

By authority of the Board.

For the Board.

Beatrice Ezerski,

Secretary to the Board.

[FR Doc. 96–12737 Filed 5–20–96; 8:45 am]

BILLING CODE 7905–01–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: Final rule.

SUMMARY: The Food and Drug Administration (FDA) has granted 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 amends FDA's regulations governing use of CFC's to include sterile aerosol talc as an essential use.

EFFECTIVE DATE: June 4, 1996.

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

In the Federal Register of March 1, 1996 (61 FR 8002), FDA published, in response to a citizen petition submitted by Bryan, a proposed rule to amend § 2.125 (21 CFR 2.125) to add sterile aerosol talc administered intrapleurally by thoracoscopy for human use to the list of products containing a CFC propellant for an essential use.

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 (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 (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. 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.

Based on the evidence before it in the petition and in Bryan's new drug application for the drug product, the agency has determined that for many patients suffering from pleural effusions, the use of sterile aerosol talc provides a special benefit that would be unavailable without the use of CFC's. 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 amending § 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 the proposed rule was provided to the Administrator. Interested persons were given 30 days to comment on the proposed rule. FDA received no comments on the proposed rule.

Analysis of Impacts

FDA has examined the impacts of the final 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 final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final 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 this final rule will have on any small entities, the agency certifies that the final 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.

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, 21 CFR part 2 is 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: May 15, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–12758 Filed 5–21–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 173

[Docket No. 93F–0483]

Secondary Direct Food Additives Permitted in Food for Human Consumption; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting the final rule that appeared in the Federal Register of March 3, 1995 (60 FR 11899). The document amended the food additive regulations to provide for the safe use of chlorine dioxide to control the microbial population in poultry process water. The document was published with some errors. This document corrects those errors. Additionally, the agency is revising some of the discussion in the preamble for clarification. These changes are not substantive and do not affect the agency's conclusion regarding the use of chlorine dioxide in poultry process water. The codified regulation remains unchanged.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204–0001, 202–418–3074.

In FR Doc. 95–5275, appearing on page 11899 in the Federal Register of Friday, March 3, 1995, the following corrections are made:

1. On page 11899, in the second column, in the first full paragraph, beginning in line 8, ''reaction of chlorine with sodium chlorite'' is corrected to read ''oxidation of sodium chlorite''; in the same paragraph, beginning in line 10, ''acidification of sodium chlorite'' is corrected to read ''disproportionation of sodium chlorite in the presence of acids (Ref. 1).''; and in the same paragraph, beginning in line 16, ''(Ref. 1).'' is corrected to read ''Ref. 1a).''

2. On page 11899, in the second column, in the second full paragraph, in line 5, ''of chlorine'' is corrected to read ''with chlorine''.

3. On page 11899, in the second column, in the fourth full paragraph, in the 4th line from the bottom, ''studies'' is corrected to read ''safety studies'' and in the 3rd line from the bottom ''petitioner were'' is corrected to read ''petitioner on poultry were''.

4. On page 11899, in the third column, in the first paragraph, in line 3, ''3 ppm'' is corrected to read ''100 ppm''.

5. On page 11899, in the third column, in the first paragraph, beginning in line 5 and ending in line 21, ''These data show that organic * * * in drinking water.)'' is corrected to read ''These data show that comparable trace levels of chloroform and dichloromethane were detected in both untreated and chlorine dioxide-treated poultry process water and that chlorine dioxide treatment did not appear to contribute to their formation.''

6. On page 11899, in the third column, in the first paragraph, in line 23, ''20'' is corrected to read ''100'', and beginning in line 24, ''no mutagenic'' is corrected to read ''negligible mutagenic''.

7. On page 11899, in the third column, in the third paragraph, beginning in line 8, ''(No chlorite or chlorate could * * * for the method used).'' is removed.

(Note: The finding of no significant residues of chlorite and chlorate was not based on chemical analysis. The agency determined that any residues of chlorite and chlorate remaining on poultry would be converted to chloride (a major component of table salt) during cooking.)

8. On page 11900, in the first column, in the first full paragraph, beginning in line 3, ''linoleic, linolenic, and arachidonic acid)'' is corrected to read ''linoleic and linolenic acid)'', and in the same paragraph, in line 11, ''levels 7 to 10 times'' is corrected to read ''levels 8 to 22 times''.

9. On page 11900, in the first column, in the second full paragraph, in line 4, ''measurable'' is corrected to read ''significant''.

10. On page 11900, in the first column, in the third full paragraph, in line 6, ''no'' is corrected to read ''negligible''.

11. On page 11900, in the third column, Ref. 1a is added to read ''1a. U.S. patent No. 4,247,531.'', and Ref. 6 is corrected to read ''6. CRC Handbook of Chemistry and Physics, 71st ed., 1990–1991, David R. Lide, Editor-in-Chief, CRC Press, Boca Raton, FL. See Table of Electrochemical Potentials (re chlorite and chlorate), sections 8–16.''

Dated: May 14, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–12757 Filed 5–20–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 176

[Docket No. 92F–0313]

Indirect Food Additives: Paper and Paperboard Components

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of diethanolamine as a boiler water additive in paper mill boilers used in the manufacture of paper and paperboard intended for use in contact with aqueous and fatty food. This action is in response to a food additive petition filed by Betz Laboratories, Inc.

DATES: Effective May 21, 1996; written objections and requests for a hearing by June 20, 1996.

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

FOR FURTHER INFORMATION CONTACT: Diane E. Robertson, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3089.