that an allotment percentage of 56 percent should be established for Scotch spearmint oil for the 1995–96 marketing year. This percentage will provide an increased calculated salable quantity of 997,317 pounds, the actual additional amount of Scotch spearmint oil being made available by this interim final rule is 67,786 pounds. This results in an actual salable quantity of 954,879 pounds of Scotch spearmint oil.

Based on available information, the Administrator of the AMS has determined that the issuance of this interim final rule will not have a significant economic impact on a substantial number of small entities.

After consideration of all relevant matter presented, including that contained in the prior proposed and final rules in connection with the establishment of the salable quantities and allotment percentages for Scotch and Native spearmint oils for the 1995–96 marketing year, the Committee's recommendation and other available information, it is found that to revise section 985.214 (60 FR 8524) to change the salable quantity and allotment percentage for Scotch spearmint oil, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

Pursuant to 5 U.S.C. 553, it is also found and determined upon good cause that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice prior to putting this rule into effect and that good cause exists for not postponing the effective date of this rule until 30 days after publication in the Federal Register because: (1) This interim final rule increases the quantity of Scotch spearmint oil that may be marketed during the marketing year beginning on June 1, 1995; (2) The quantity of Scotch spearmint planted for the 1996–97 marketing year may be affected, thus handlers and producers should be apprised as soon as possible of the salable quantity and allotment percentage of Scotch spearmint oil contained in this interim final rule; and (3) This rule provides a 30-day comment period and any comments received will be considered prior to finalization of this rule.

List of Subjects in 7 CFR Part 985

Marketing agreements, Oils and fats, Reporting and recordkeeping requirements, Spearmint oil.

For the reasons set forth in the preamble, 7 CFR part 985 is amended as follows:

PART 985—SPEARMINT OIL PRODUCED IN THE FAR WEST

1. The authority citation for 7 CFR part 985 continues to read as follows:

Authority: 7 U.S.C. 601–674.

2. Section 985.214 is amended by revising paragraph (a) to read as follows:

Note: This section will not appear in the annual Code of Federal Regulations.

§ 985.214 Salable quantities and allotment percentages-1995–96 marketing year.

The salable quantity and allotment percentage for each class of spearmint oil during the marketing year beginning on June 1, 1995, shall be as follows:

(a) Class 1 (Scotch) oil—a salable quantity of 997,317 pounds and an allotment percentage of 56 percent.

* * * * *

Dated: April 2, 1996.

James R. Rodeheaver,

Acting Deputy Director, Fruit and Vegetable Division.

[FR Doc. 96–8719 Filed 4–8–96; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF COMMERCE

Bureau of the Census

15 CFR Part 30

[Docket No. 960329093–6093–01]

RIN 0607–XX13

Collection of Canadian Province of Manufacture Information for Softwood Lumber on Customs Entry Records

AGENCY: Bureau of the Census, Commerce.

ACTION: Final rule with request for comments.

SUMMARY: The Bureau of the Census (Census) has directed the U.S. Customs Service (Customs) to begin immediate collection of information on the province of manufacture on imports of softwood lumber from Canada. This action is taken to assist in carrying out an agreement reached between the United States and Canada concerning trade in softwood lumber.

DATES: Final rule effective April 5, 1996. Comments due on or before May 6, 1996.

ADDRESSES: Direct all written comments to the Director, Bureau of the Census, Room 2049, Federal Building 3, Washington, DC 20233.

FOR FURTHER INFORMATION CONTACT: C. Harvey Monk, Jr., Bureau of the Census, Washington, D.C. 20233, by telephone on (301) 457–2255 or by fax (301) 457–2645. For information on the U.S.-Canada agreement on softwood lumber: Gordana Earp, Deputy Assistant U.S. Trade Representative for Industry, by telephone on (202) 395–6160.

SUPPLEMENTARY INFORMATION:

Background

On February 19, 1996, the United States and Canada concluded an agreement in principle on trade on certain softwood lumber products. Upon completion of the agreement text, the agreement is to enter into force, in fact, on April 1, 1996. The agreement includes commitments by Canada that are linked to the amount of softwood lumber exported annually to the United States from particular provinces. To carry out the agreement, it is necessary to determine accurately the amount of softwood lumber entering the United States on a province-by-province basis.

Currently, U.S. Customs entry records include information on the Identification of the Foreign Manufacturer. This information is not satisfactory because it frequently represents the corporate headquarters or Canadian vendor, and not the location in which the goods were actually produced.

Effective April 5, 1996 unless notified by the United States Trade Representative of a later effective date, the Bureau of the Census will require the two-letter designation of the Canadian province of manufacture to be reported on U.S. entry summary records for shipments released on or after April 5, 1996. The province of manufacture is to be determined on a first mill basis (i.e., the point at which the item was first manufactured into a covered lumber product (described below)). Further processing (e.g., planing or kiln drying) and/or transformation from one covered lumber product into another covered lumber product (e.g., remanufactured products) in another province does not constitute a change in the province of manufacture. For purposes of this rule, province of manufacture is the province where the subject merchandise underwent a change in tariff classification to tariff items 4407.1000, 4409.1010, 4409.1090, or 4409.1020 from any other tariff items except a tariff item within that group.

The reporting of province of manufacture will apply to the non-ABI as well as ABI entry summaries. For those reporting on paper forms the province of manufacture code will replace the Country of Origin on the CF 7501 Entry Summary form. This requirement would apply only for imports of softwood lumber with Country of Origin Canada.

All electronic ABI Entry Summaries transmitted with the Country of Origin Canada would also require the new Canadian province of manufacture code. The Country of Origin is transmitted for each entry summary line item in the A 40 record positions 6–7. For imports of softwood lumber from Canada, the province of manufacture code should replace Country of Origin in positions 6–7 of the A 40 record.

Valid Canadian province/territory codes are:

XA—Alberta
XB—New Brunswick
XC—British Columbia
XM—Manitoba
XN—Nova Scotia
XO—Ontario
XP—Prince Edward Island
XQ—Quebec
XS—Saskatchewan
XT—Northwest Territories
XW—Newfoundland
XY—Yukon Territory

The authority to collect this information is provided under Title 13, United States Code, Section 301, which authorizes the Secretary of Commerce to collect information from persons importing into, or exporting from the United States, as he deems necessary or appropriate to foster, promote, develop, and further the commerce, domestic and foreign, of the United States.

The information is to be collected as part of that required on the Customs CF 7501 paper or ABI automated entry record. This reporting is required by the Customs Service for each importation of foreign merchandise and occurs at the time of importation.

The products covered by this rule are certain softwood lumber products. These lumber products include: (1) Coniferous wood, sawn or chipped lengthwise, sliced or peeled, whether or not planed, sanded or finger-jointed, of a thickness exceeding six millimeters; (2) coniferous wood siding (including strips and friezes for parquet flooring, not assembled) continuously shaped (tongued, grooved, rabbetted, chamfered, V-jointed, beaded, molded, rounded or the like) along any of its edges or faces, whether or not planed, sanded, or finger-jointed; and (3) other coniferous wood (including strips and friezes for parquet flooring, not assembled) continuously shaped (tongued, grooved, rabbetted, chamfered, V-jointed, beaded, molded, rounded or the like) along any of its edges or faces, whether or not planed, sanded or finger-jointed; and (4) coniferous wood flooring (including strips and friezes for parquet flooring, not assembled) continuously shaped (tongued, grooved, rabbetted, chamfered, V-jointed, beaded, molded, rounded or the like) along any of its edges or faces, whether or not planed, sanded, or finger-jointed. Such products are currently provided for under subheading 4407.1000, 4409.1010, 4409.1090 and 4409.1020, respectively of the Harmonized Tariff Schedule of the United States (HTSUS).

Rulemaking Requirements

1. This final rule is exempt from the requirements of Executive Order 12866.

2. This rule involves a collection of information subject to the Paperwork Reduction Act of 1995. This collection has been approved by the Office of Management and Budget (OMB) under control number 1515–0065. The United States Customs Service form CF 7501 and the associated electronic reporting form A 40 are estimated to average 20 minutes per response. This estimate includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collections of information. Send comments regarding this estimate to Phillip Metzger, Director of Trade Compliance, U.S. Customs Service, Department of the Treasury, 1301 Constitution Ave., N.W., Washington, DC 20229–0001. Notwithstanding any other provisions of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number.

3. This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 12612.

4. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule under 5 U.S.C. 553(a)(1) or by any other law, under section 3(a) and 4(a) of the Regulatory Flexibility Act (5 U.S.C. 603(a) and 604(a)) no initial or final Regulatory Flexibility Analysis has to be or will be prepared.

5. The provisions of the Administrative Procedure Act, (5 U.S.C. 553), requiring notice of proposed rulemaking, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military or foreign affairs function of the United States (see 5 U.S.C. 553(a)(1)). No other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule.

However, because of the importance of the issues raised by this regulation, this rule is issued in final and comments will be considered. The period for submission of comments will close May 6, 1996. Direct all written comments to the Director, Bureau of the Census, Room 2049, Federal Building 3, Washington, DC 20233.

List of Subjects in 15 CFR Part 30

Economic statistics, Foreign trade, Reporting and recordkeeping requirements.

For reasons set out in the preamble, 15 CFR part 30 is amended as follows:

PART 30—FOREIGN TRADE STATISTICS

1. The authority citation for 15 CFR part 30 continues to read as follows:

Authority: 5 U.S.C. 301; 13 U.S.C. 301–307; Reorganization Plan No. 5 of 1950 (3 CFR 1949–1953 Comp., p. 1004); Department of Commerce Organization Order No. 35–2A, August 4, 1975, 40 CFR 42765.

Subpart F—Special Provision for Particular Types of Import Transactions

2. Section 30.80 is added to subpart F to read as follows:

§ 30.80 Imports from Canada.

When certain softwood lumber products described under Harmonized Tariff Schedule of the United States (HTSUS) subheadings 4407.1000, 4409.1010, 4409.1090, and 4409.1020, are imported from Canada; import entry records are required to show a valid Canadian Province of Manufacture Code. The Canadian Province of Manufacture is determined on a first mill basis (the point at which the item was first manufactured into a covered lumber product). For purposes of determination, Province of Manufacture is the first province where the subject merchandise underwent a change in tariff classification to the tariff classes cited above. The Province of Manufacture Code should replace the Country of Origin on the CF 7501 Summary Entry form. For Automated Commercial System entry summaries the Canadian Province Code should be transmitted in lieu of the Country of Origin in positions 6–7 of the A 40 record. These requirements would apply only for imports of softwood products with Country of Origin Canada. Valid Canadian Province/Territory Codes are:

XA—Alberta
XB—New Brunswick
XC—British Columbia

XM—Manitoba
XN—Nova Scotia
XO—Ontario
XP—Prince Edward Island
XQ—Quebec
XS—Saskatchewan
XT—Northwest Territories
XW—Newfoundland
XY—Yukon Territory

Dated: March 29, 1996.

Martha Farnsworth Riche,

Director, Bureau of the Census.

[FR Doc. 96–8925 Filed 4–5–96; 4:14 pm]

BILLING CODE 3510–07–P

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: Final rule.

SUMMARY: The Food and Drug Administration (FDA) has granted 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 amends 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.

EFFECTIVE DATE: April 9, 1996.

FOR FURTHER INFORMATION CONTACT: Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD–097), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1049.

SUPPLEMENTARY INFORMATION:

I. Background

In response to a citizen petition submitted by BIPI, in the Federal Register of October 17, 1995 (60 FR 53725), FDA published a proposed rule to amend 1A2.125 (21 CFR 2.125) to add metered-dose albuterol sulfate and ipratropium bromide in combination for oral inhalation to the list of productscontaining a CFC propellant for an essential use.

Under 1A2.125, 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 1A2.125(c) certain products containing CFC propellants thatFDA 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 1A2.125(e).

Under 1A2.125(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 1A2.125(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 1A2.125(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 found in brackets 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. 10923, Rockville, MD 20857. The petition requested that metered-dose albuterol sulfate and ipratropium bromide in combination for oral inhalation be included in 1A2.125(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 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 andipratropium 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.

The agency has determined 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,