widely available for purchase, and a healthy level of competition exists among manufacturers capable of maintaining a current and adequate stock of response equipment at increased levels. The overall availability of new oil spill response equipment in the commercial market has improved since 1993.

The availability of existing equipment stocks for deployment to spills was assessed by reviewing nationwide inventories of major items such as booms, skimmers, skimming vessels, and temporary storage devices. Primary data was compiled using the Coast Guard National Strike Force Coordination Center's (NSFCC) Response Resource Inventory (RRI). The resulting equipment distribution and the daily recovery capacity it represented were examined for each geographic region and operating environment. The comparison of the scheduled cap increase with the existing equipment stocks available to planholders clearly indicated that planning for a response is not equipment limited. The scheduled 25 percent cap increase can easily be accommodated with the existing stocks of equipment available to planholders for each geographical region and operating environment.

The assessments of technological capability, market availability, and regional availability of existing stocks, support the determination that the scheduled increase in caps is practicable. For a more detailed explanation of these findings, the Cap Review can be viewed on the Internet at the sites listed in the **ADDRESSES** section.

Other removal technologies. The Cap Review also evaluated the following topics:

a. Additional proposed increases for on-water mechanical removal capacity in 2003.

b. Advances in oil tracking technology.

c. Improvements in high-rate removal technologies such as dispersants or in situ burning.

The conclusions and recommendations of the Cap Review concerning these topics are contained within the Response Plan Equipment Cap Review document. This notice does not address these topics and makes no changes to existing regulations or policy. However, we intend to address any additional cap increases for mechanical recovery or other removal technologies in a subsequent rulemaking. The Cap Review recommendations regarding these other removal technologies should be viewed as information only. We will consider them along with previously received public comments when formulating any subsequent rulemakings.

Dated: December 28, 1999.

Joseph J. Angelo,

Acting Assistant Commandant for Marine Safety and Environmental Protection.

[FR Doc. 00–31 Filed 1–5–00; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[FRL–6519–3]

RIN 2060–AI73

Protection of Stratospheric Ozone: Allocation of Essential Use Allowances for Calendar Year 2000: Allocations for Metered-Dose Inhalers and the Space Shuttle and Titan Rockets

AGENCY: Environmental Protection Agency (EPA).

ACTION: Interim final rule.

SUMMARY: With this action, EPA is allocating essential-use allowances for calendar year 2000 for ozone depleting substances (ODS) for use in medical devices and for use in the Space Shuttle Rockets and Titan Rockets for the year 2000 control period. Production and import of ODS for laboratory and analytical applications will be addressed in a separate rulemaking. The United States nominated specific uses of controlled ozone-depleting substances as essential for calendar year 2000 under the Montreal Protocol on Substances that Deplete the Ozone Layer (Protocol). The Parties to the Protocol subsequently authorized specific quantities of ODS for calendar year 2000 for the uses nominated by the United States. EPA allocates essential use allowances to an applicant for exempted production or import of a specific quantity of controlled substances solely for the designated essential purpose. These essential use allowances permit a person to obtain controlled ODS as an exemption to the January 1, 1996, regulatory phaseout of production and import.

DATES: This action is effective January 6, 2000. EPA will consider all written comments received by February 7, 2000 to determine if any change to this action is necessary.

ADDRESSES: Those wishing to notify EPA of their intent to submit adverse comments on this action should contact Erin Birgfeld, U.S. Environmental Protection Agency, Stratospheric Protection Division, Office of Air and Radiation (6205J), Ariel Rios Building, 1200 Pennsylvania Avenue, NW., Washington, DC, 20460; <birgfeld.erin@epa.gov >; (202) 564–9079 phone and (202) 565–2096 fax. Materials relevant to this rulemaking are contained in Docket No. A–92–13. The Docket phone is (202) 260–7548 and is located in room M–1500, First Floor, Waterside Mall 401 M Street, SW., Washington, DC 20460. The materials may be inspected from 8 a.m. until 4 p.m. Monday through Friday. A reasonable fee may be charged by EPA for copying docket materials.

FOR FURTHER INFORMATION CONTACT: The Stratospheric Ozone Protection Hotline at (800) 296–1996 or Erin Birgfeld, U.S. Environmental Protection Agency, Stratospheric Protection Division, Office of Air and Radiation (6205J), Ariel Rios Building, 1200 Pennsylvania Avenue, NW., Washington, DC, 20460; <*birgfeld.erin@epa.gov* >; (202) 564–9079 phone and (202) 565–2096 fax.

SUPPLEMENTARY INFORMATION:

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I. Background

Overview of the Notice of Proposed Rulemaking

The Notice of Proposed Rulemaking (NPRM) for allocating essential use allowances was published on November 2, 1999 (64 FR 59141). In the NPRM, EPA proposed allocating chlorofluorocarbon (CFCs) for use in metered dose inhalers (MDIs), and methyl chloroform for use in the Space Shuttle and Titan Rocket. EPA explained that because of additional requirements in the Clean Air Act that apply beginning in calendar year 2000, before allocating CFCs for use in MDIs, EPA must receive a determination from the Food and Drug Administration (FDA) indicating the amount of CFCs that are necessary for use in MDIs. The quantities of CFCs proposed to be allocated were the quantities that were agreed upon at the Eighth Meeting of the Parties to the Montreal Protocol. FDA's determination of the amount of CFCs that are necessary for use in MDIs, which EPA has subsequently received, is substantially lower than what was proposed in the NPRM. The allocations

in this action reflect these lowered amounts. Because stakeholders have not had a chance to comment on the lower amounts, today's action is being issued as an interim final rule effective January 6, 2000. This will allow essential use applicants access to necessary CFCs for continued production of MDIs, and at the same time will allow for further comment on and potential changes to the allocation.

In the NPRM, EPA also explained that due to requirements of the CAA that apply beginning in calendar year 2000, the essential use exemption for import and production of small amounts of high purity ozone depleting substances (ODS) for laboratory and analytical uses may not be available after January 1, 2000. Today's action does not address this issue. EPA will issue a separate final rule on the topic of laboratory essential uses.

Overview of the Essential Use Process

The Montreal Protocol on Substances that Deplete the Ozone Layer (Protocol) sets specific deadlines for the phaseout of production and importation of ozone depleting substances (ODS). At their Fourth Meeting in 1992, the Parties to the Protocol (the Parties) amended the Protocol to allow exemptions to the phaseout for uses agreed by the Parties to be essential. At the same Meeting, the Parties also adopted Decision IV/25, which established criteria for determining whether a specific use should be approved as essential, and the process for making such a determination.

The criteria for an essential use as set forth in Decision IV/25 are the following:

''(1) that a use of a controlled substance should qualify as 'essential' only if:

(i) it is necessary for the health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects); and

(ii) there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health;

(2) that production and consumption, if any, of a controlled substance for essential uses should be permitted only if:

(i) all economically feasible steps have been taken to minimize the essential use and any associated emission of the controlled substance; and

(ii) the controlled substance is not available in sufficient quantity and quality from existing stocks of banked or recycled controlled substances, also bearing in mind the developing countries' need for controlled substances.''

The procedure set out by Decision IV/25 first calls for individual Parties to nominate essential uses. The Protocol's Technology and Economic Assessment Panel (TEAP or the Panel) evaluates the nominated essential uses and makes recommendations to the Protocol Parties. The Parties make the final decisions on essential use nominations at their annual meeting.

Persons requesting essential use exemptions submit applications which respond to the specific questions in the 1997 Handbook on Essential Use Nominations. This document may be obtained from the Stratospheric Protection Division, U.S. Environmental Protection Agency or the Ozone Secretariat of the Montreal Protocol in Nairobi. The Handbook can also be downloaded from the TEAP website at: http://www.teap.org/html/teap__reports.html.

What does EPA do with the information in the essential use applications?

The U.S. EPA carefully reviews all the information in each essential use application and enters the information into a tracking system which permits year by year comparison of quantities of ODS requested, quantities allocated, quantities of ODS received in previous years, and quantities of ODS used for the specific essential activity. The review of data enables EPA to assess whether entities are stockpiling ODS, whether there seem to be inflated requests relative to actual use, and whether there is possible double-counting between companies. For example, in 1998 we identified some double-counting in the requests for CFCs among companies. Our analysis also revealed that there were disparities between the total quantity of CFCs requested for MDIs and the actual quantity used to manufacture MDIs in previous years. To account for this inflation in the request for allocation, EPA reduced the total U.S. nomination for 1998 by 10 percent before forwarding the applications for consideration by the TEAP and the Parties to the Protocol.

Every year since 1994, EPA has reviewed applications for essential uses according to the above criteria and then forwarded the applications to the Parties. The Parties then review the recommendations by the TEAP and make final decisions on essential use nominations.

What are the essential uses that EPA has nominated in the past?

Decision IV/25 was implemented initially in the context of halons which were phased out of production at the end of 1993. At that time, nominations for halons were separated from those for other ozone-depleting substances. EPA issued a **Federal Register** notice requesting nominations for essential uses of halons (February 2, 1993; 58 FR 06786). In response, the Agency received over ten nominations, but was able to work with applicants to resolve their near-term requirements. As a result, the U.S. did not nominate any uses for continued halon production in 1994. About a dozen other nations put forth nominations which were reviewed by the Panel, which determined that in each case alternatives existed or that the existing supply of banked halons was adequate to meet near-term needs. The Panel, therefore, did not recommend approval for any of the nominations. In November of 1993, at the Fifth Meeting, the Parties unanimously adopted the Panel's recommendation not to approve any essential uses for production and consumption of halons in 1994.

EPA issued a second notice requesting applications for essential use applications for halons for the 1995 control period on October 18, 1993 (58 FR 53722). In response to this inquiry, EPA received no applications. The TEAP received only one nomination (from France) for essential use exemptions for halons for production and consumption of halons for an essential use in 1995. The TEAP did not recommend approval of this nomination.

In 1993, EPA issued a **Federal Register** notice requesting essential use applications for CFCs, methyl chloroform, carbon tetrachloride, and hydrobromofluorocarbons required beyond the 1996 phaseout of consumption and production of these class I substances (May 20, 1993, 58 FR 29410). EPA received 20 applications in response to this notice. For several of these applications, EPA determined that the criteria contained in Decision IV/25 had not been satisfied. For example, EPA rejected two applications seeking CFCs for use in servicing air-conditioning equipment on the basis that adequate supplies of banked and recycled CFCs were available. However, in rejecting these nominations, the United States noted that servicing existing air-conditioning and refrigeration equipment remains a major challenge to the successful transition from ODSs and that a future nomination in this area might be necessary if a

combination of retrofits, replacements, recycling, recovery at disposal, and banking do not adequately address these needs.

In 1993, the United States forwarded essential use nominations to the Protocol Secretariat for the following uses of CFCs: metered dose inhalers and other selected medical applications; rocket motor assembly for the Space Shuttle; aerosol wasp killers; limited use in a specified bonding agent and polymer application; and a generic application for laboratory uses under specified limitations. (Letter from Pomerance to the United Nations Environment Programme (UNEP), September 27, 1993).

The TEAP reviewed over 200 specific uses which were submitted to the Montreal Protocol Secretariat by the Parties to the Protocol. In March 1994, the Panel issued the ''1994 Report of the Technology and Economic Assessment Panel,'' which included the Panel's recommendations for essential-use production and consumption exemptions. The Panel recommended that essential use exemptions be granted for nominations of: methyl chloroform in solvent bonding for the Space Shuttle; CFCs used in metered dose inhalers; and specific controlled substances needed for laboratory and analytical applications. For each of the other nominations submitted, the TEAP determined that one or more of the criteria for evaluating an essential use had not been satisfied. The Parties approved essential use exemptions for the uses recommended in the 1994 TEAP report. The U.S. has continued to request and receive exemptions for those same uses in subsequent years.

II. Allocation Process for the Calendar Year 2000

The domestic allocation process for this year differs from past allocations due to changes in the requirements under the Clean Air Act (CAA or the Act). The purpose of this section is to explain the legal background behind these changes, and to outline the procedures that EPA and the Food and Drug Administration (FDA) used to fulfill our obligations under the CAA in allocating ozone depleting substances for calendar year 2000.

Prior to the year 2000, EPA allocated essential use exemptions under the original phase-out schedule contained in section 604 of the Act. This schedule does not require the complete phaseout of any ODS prior to calendar year 2000. Under section 606 of the Act, EPA was obligated to create an accelerated phaseout through regulation to match the accelerated phaseout under the Protocol. However, EPA had the flexibility to create exemptions to the regulatory phaseout, where such exemptions had been approved under the Montreal Protocol. Thus, for the past several years, EPA has been able to authorize production and import of ozone-depleting substances for essential uses allowed under the Protocol, without regard to whether the Act contains exceptions for those uses, as long as the total authorized production does not exceed the amount permitted by the Act. However, January 1, 2000, is the phaseout date under Section 604 of the Act for all class I substances with the exception of methyl chloroform and methyl bromide. The phaseout dates for methyl chloroform and methyl bromide are January 1, 2002 and January 1, 2005, respectively. After the phaseout date for a particular substance has passed, EPA will no longer be able to authorize production of that substance on the basis of the slower phaseout schedule under the Act. Because CFCs are to be phased-out by calendar year 2000 under the original phase-out schedule, EPA must now implement essential use exemptions for these chemicals as specified under the Act in section 604(d).

The phaseout date for methyl chloroform under the Act is January 1, 2002. Until that date, the Act permits production and import of methyl chloroform equivalent to 20% of baseline. The amount of methyl chloroform allocated for calendar year 2000 is well below this limit. Beginning in the year 2002, EPA will implement the exception for essential uses of methyl chloroform found in 604(d)(1) of the Act.

For calendar year 2000, the entities in Table I submitted applications requesting class I controlled substances for essential uses. The applications provided information in accordance with the criteria set forth in Decision IV/25 of the Protocol and the procedures outlined in the ''1997 Handbook on Essential Use Nominations.'' The applications requested exemptions for the production and import of specific quantities of certain class I controlled substances after the phaseout. The EPA reviewed the applications and nominated these uses to the Protocol Secretariat for analysis by the TEAP and its Technical Option Committees (TOCs). The Parties to the Montreal Protocol approved the U.S. nominations for essential-use exemptions during the Tenth Meeting in 1998 (Decision IX/18). Today's action allocates essential-use allowances to U.S. entities as authorized by the Parties to the Montreal Protocol and to the extent consistent with the CAA.

The Act provides for the following essential use exemptions to the ban on production and import. Section 604 (d)(2) states that notwithstanding the phaseout, EPA shall, to the extent consistent with the Montreal Protocol, authorize production of limited quantities of class I substances for use in medical devices, if FDA, in consultation with EPA, determines that such production is necessary. Section 604(d)(3) states that EPA may, to the extent consistent with the Montreal Protocol, authorize production of limited quantities of halon-1211, halon-1301, and halon-2402 solely for the purpose of aviation safety, if the Federal Aviation Administration, in consultation with EPA, determines that no safe and effective substitute has been developed and that such authorization is necessary for aviation safety purposes. Section 604(d)(1) provides that during the period from January 1, 2002 to January 1, 2005, EPA may, to the extent consistent with the Montreal Protocol, authorize the production of limited quantities of methyl chloroform solely for use in essential applications for which no safe and effective substitute is available. Section 604(d)(4) states that EPA cannot use any of these three exemptions to authorize any person to produce a class I substance in annual quantities greater than 10 percent of that person's baseline year as defined in Section 601(2). Section 604(g)(3) of the Act provides that EPA may, to the extent consistent with the Montreal Protocol, authorize the production of limited quantities of halon-1211, halon-1301, and halon-2402 after December 31, 1999, and before December 31, 2004 for use in fire suppression and explosion prevention in association with domestic production of crude oil and natural gas energy supplies on the North Slope of Alaska, if it is determined that no safe and effective substitute has been developed and that such authorization is necessary for fire suppression or explosion prevention purposes. EPA cannot use this exemption to authorize any person to produce any of these halons in an amount greater than 3 percent of that person's baseline. Finally, section 604(f) states that the President may, to the extent consistent with the Montreal Protocol, provide an exemption for production of CFC -114, halon-1211, halon-1301, and halon-2402 as necessary to protect U.S. national security interests, if the President finds that adequate substitutes are not

available and that the production and use of the substance are necessary to protect national security interests.

Today's action allocating CFCs for use in MDIs requires EPA to implement the exception for medical devices found in section 604(d)(2) of the Clean Air Act. ''Medical device'' is defined in section 601(8) of the Clean Air Act as follows:

[A]ny device (as defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321), diagnostic product, drug (as defined in the Federal Food, Drug, and Cosmetic Act), and drug delivery system—

(A) if such device, product, drug, or drug delivery system utilizes a class I or class II substance for which no safe and effective alternative has been developed, and where necessary, approved by the Commissioner [of FDA]; and

(B) 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 [of FDA] in consultation with the Administrator [of EPA].

The preamble to FDA's September 1, 1999, notice of proposed rulemaking on essential use determinations (64 FR 47735) discusses FDA's approach to determining whether ''safe and effective alternative[s]'' have been developed. It states that ''A non-CFC product simply having the same active moiety as a CFC product is only one factor to be considered. Other factors, such as whether the non-CFC product has the same route of administration, the same indication, and can be used with approximately the same level of convenience, are important considerations. Additionally, FDA must consider whether patients who medically need the CFC product are adequately served by the non-CFC product. FDA's approval of a non-CFC product is a determination that the product is safe and effective, but it is not a determination that the product is a safe and effective alternative to any other product. That requires a separate and distinct analysis.'' FDA has not yet determined that any non-CFC product is a safe and effective alternative to any CFC MDI. Accordingly, part (A) of the definition of medical device has not affected today's allocation.

With respect to part (B) of the definition of medical device (section 601(8)(B)), and in particular the use of the word ''essential'' in that part of the definition, EPA is relying on current FDA regulations (21 CFR 2.125) which contain a list of uses of CFCs that FDA in consultation with EPA has found to be essential. This list includes, among others, metered-dose steroids, metered-dose adrenergic bronchodilators, metered-dose cromolyn sodium, metered-dose ipratropium bromide, and metered-dose nedocromil sodium, all drugs for oral inhalation in humans. The companies for which EPA is granting essential use allowances produce CFC MDIs that contain these active moieties. Thus, the products for which EPA is granting essential use allowances are ''determined to be essential'' by FDA.

Also with respect to part (B) of the definition of ''medical device'', EPA and FDA considered how to interpret the language regarding approval by FDA of the ''device, product, drug, or drug delivery system.'' The complete phrase reads as follows: ''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.'' The decision was made to interpret this phrase as referring to FDA's approval of an essential use and not the approval of the specific product in question through approval of the New Drug Application (NDA) or Abbreviated New Drug Application (ANDA) for that product. This means that any MDI whose active moiety appears on FDA's essential use list is eligible to receive essential use allowances. This interpretation was taken for the following reasons. The term ''approved'' must be interpreted in light of the surrounding language. Section 601(8)(B) requires notice and comment rulemaking and refers to action by FDA, in consultation with EPA. Since approval of an NDA or ANDA under the FDCA involves unilateral action by FDA without notice-and-comment rulemaking, it is reasonable to conclude section 601(8)(B) does not refer to approval of an NDA or ANDA under the FDCA. Therefore, FDA and EPA are interpreting section 601(8)(B) to refer to FDA's approval of an essential use. This interpretation is consistent with the surrounding language, since FDA engages in notice-and comment rulemaking in listing essential uses and since EPA has a strong interest in decisions about essential uses. This means that an MDI is ''approved and determined to be essential'' if the MDI contains an active moiety on FDA's essential use list. All of the MDIs for which we are allocating CFCs today meet this qualification.

Implementing the essential use exemption for MDIs under the Act required EPA to consult with FDA regarding the quantity of CFCs to be allocated. As stated earlier, section 604(d)(2) of the Act provides that EPA shall authorize production and import of limited quantities of class I substances for use in medical devices if FDA, in consultation with EPA, determines such authorization to be necessary. Administrator Carol Browner sent a letter to Dr. Jane Henney, Commissioner of FDA, dated October 28, 1999, requesting that FDA make a determination on the amount of CFCs that are ''necessary'' for the production of MDIs for calendar year 2000. A December 23, 1999, letter was sent in response from Commissioner Henney that contains FDA's determination.

EPA also collected additional information relevant to the allocation. The 1997 TEAP Handbook on Essential Use Nomination (Handbook), the guidance document for essential use exemption applications, does not request information regarding specific products for which the CFCs will be used. As a result, EPA sought more detailed information including which drug products would be produced using the allocated CFCs for calendar year 2000. EPA sent out letters to the essential use applicants (separate letters were sent to the International Pharmaceutical Aerosol Consortium (IPAC) member companies) for medical devices, requesting this additional information under section 114 of the Act. The responses to the letters included confidential business information on the types of drug products to be manufactured, as well as the quantity and the specific CFC chemical to be used in the manufacture of each product. EPA shared the responses to these letters with FDA to assist it in determining the amount of CFCs for use in medical devices that are ''necessary.''

Dr. Henney's letter in response to the Administrator dated December 23, 1999, provided FDA's analysis of the amounts of CFCs that FDA determined are necessary in calendar year 2000 for the production of medical devices as defined under the Clean Air Act. FDA determined that a total of 2737.3 metric tons are necessary for use in MDIs for calendar year 2000. In contrast, the total amount of CFCs proposed to be allocated in the NPRM (November 2, 1999 64 FR 59141) was 3735 metric tons. The rationale underlying FDA's determination is provided in Dr. Henney's December 23, 1999 letter:

''In listing the amounts we believe to be necessary for use in medical devices, we referred to historical use and have included an additional amount to allow for overage, for waste during manufacturing, for uncertainties in the

supply chain of CFCs since they are no longer produced in the United States, for changes in future market shares of specific products, as well as for unforeseen circumstances in the market. We also provided additional amounts based on our knowledge of certain manufacturing problems. In addition, we eliminated any double-counting we found and eliminated allocations for uses not considered essential by the parties to the Montreal Protocol, even if those uses are currently listed in our regulation at 21 CFR 2.125(e).'' FDA also noted that they accounted for CFCs for use in the production of MDIs that would ultimately be exported to Canada.

FDA's determination that 2737.3 metric tons of CFCs are necessary for use in MDIs is consistent with EPA's data on historical use and import for MDIs. In order for companies to place an order for CFCs they must provide a letter from EPA which indicates the amount of CFC that they are allowed to purchase from chemical producers. Before issuing these letters, EPA asks companies if they still need the entire allocation of CFCs. In many cases, companies voluntarily give up part of their CFC allocation for various reasons. The net result is that the amount of CFCs actually purchased each year is substantially less than the amount of CFCs allocated each year. For example, in 1998, 4,363 tons of CFCs were allocated for use in medical devices. However, only 2,235.6 tons were actually imported or produced for MDIs in that year, and a total of 2,425.5 tons were actually used in the production of MDIs. Similarly in 1997, 4,656.0 tons of CFCs were allocated for use in MDIs while 2,032.3 tons were imported or produced, and 2,255.1 tons were used in MDI production (data from the EPA CFC accounting framework). Thus, the amount of CFCs that FDA has determined is ''necessary'' is about 300 metric tons higher than EPA's data on actual use of CFCs in MDIs for 1998. As stated in the letter from FDA, this additional amount will act as a safety factor accounting for any unplanned interruptions in CFC supply that could occur during the course of the year.

As mentioned above, section 604(d)(2) of the Act states that EPA's allocation must be consistent with the Montreal Protocol. Article 2A(4) of the Protocol states that Parties such as the United States may not produce or import CFCs after January 1, 1996, except that the Parties may decide collectively to permit a specified amount of production or import for uses that they agree to be essential. The Parties to the Protocol approved the U.S. nominations for essential use exemptions for calendar year 2000 during their Tenth Meeting in 1998 (Decision IX/8). The quantities we are allocating today do not exceed the amounts approved by the Parties. Therefore, we believe that this action is consistent with the Protocol.

Can I Submit Comments on This Interim Final Eule?

In the interest of maintaining as open and transparent a process as possible, this year's allocation for medical devices and the space program is being issued as an interim final rule instead of a final rule. This will allow stakeholders to comment on the appropriateness and accuracy of the allocation while still allowing pharmaceutical companies access to CFCs in the near term for continued manufacture of MDIs. Today's action allocates 2737.3 tons of CFCs for use in medical devices instead of the 3735 metric tons proposed in the NPRM. EPA received no comments on the NPRM stating that the proposed allocation was insufficient for an applicant's needs. While we are accepting comment on the lowered allocation figures, EPA, under the terms of the Montreal Protocol cannot allocate CFCs in an amount higher than 3735 metric tons because no more than that amount has been approved for essential use by the Parties to the Montreal Protocol. Because we are issuing this action as an interim final rule, the following paragraphs explain the relevant procedures under the CAA and the Administrative Procedures Act (APA), as well as EPA's findings.

Section 307(d) of the CAA states that in the case of any rule to which section 307(d) applies, notice of proposed rulemaking must be published in the **Federal Register** (CAA 307(d)(3)). The promulgation or revision of regulations under title VI of the CAA is generally subject to section 307(d). However, section 307(d) does not apply to any rule referred to in subparagraphs (A) or (B) of section 553(b) of the Administrative Procedures Act (APA), 5 U.S.C. 551 *et seq.*

Section 553 of the Administrative Procedures Act, 5 U.S.C. 553(b)(B), provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, the agency may issue a rule without providing notice and opportunity for public comment. In its proposed rule, 64 FR 59141 (Nov. 2, 1999), EPA provided notice that the allocation of essential use allowances for MDIs for calendar year 2000 would be made in accordance with CAA sections 601(8) and 604(d)(2). EPA also provided preliminary interpretations of the relevant statutory language and announced that the final allocation would be based on what FDA determined was ''necessary'' under section 604(d)(2) of the CAA. The proposed allocation reflected the quantities of CFCs that had been approved by the Parties to the Montreal Protocol for this use. Because the quantities that appear in today's allocation differ significantly from the quantities that appeared in the proposal, EPA has decided to provide an opportunity for post-promulgation comment on this allocation.

EPA has determined that there is good cause for making today's allocation final without prior notice of FDA's determination or an opportunity to comment on the allocation, as adjusted to reflect FDA's determination. The allocation of these essential-use allowances to the specified MDI manufacturers will allow for the pharmaceutical industry to continue to produce life-saving MDIs for the treatment of asthma and chronic obstructive pulmonary disease. Thus, prior notice and an opportunity to comment with regard to today's allocated quantities are impracticable and contrary to the public interest. EPA finds that this constitutes good cause under 5 U.S.C. 553(b)(B). Nonetheless, EPA is providing 30 days for submission of public comments following today's action. EPA will consider all written comments submitted in the allotted time period to determine if any change to this action is required.

Section 553(d) of the APA generally provides that rules may not take effect earlier than 30 days after they are published in the **Federal Register**. However, APA section 553(d) excepts from this provision any action that grants or recognizes an exemption or relieves a restriction. Since today's action grants an exemption to the phaseout of production and consumption of CFCs, EPA is making this action effective immediately to ensure the availability of CFCs for medical devices during the 2000 control period.

III. Allocation of Essential Use Allowances for Calendar Year 2000

What Is EPA's Proposed Essential Use Allocation for Calendar Year 2000?

In today's action, EPA is allocating essential use allowances for the year 2000 control period to entities listed in Table I for exempted production or import of the specific quantity of class

I controlled substances solely for the specified essential use. The final allocation for CFCs for use in MDIs reflects FDA's determination of the amounts of CFCs that are necessary as specified under section 604(d)(2) of the Act.

TABLE I.—ESSENTIAL USE ALLOCATION FOR CALENDAR YEAR 2000

Company	Chemical	Quantity (metric tons)
(i) Metered Dose Inhalers for Treatment of Asthma and Chronic Obstructive Pulmonary Disease		
International Pharmaceutical Aerosol Consortium (IPAC)—Medeva Americas, Inc., Boehringer Ingelheim Pharmaceuticals, Glaxo Wellcome, Rhone-Poulenc Rorer, 3M.	CFC–11	381.0
	CFC–12	1169.0
	CFC–114	89.0
Medisol Laboratories, Inc.	CFC–11	13.0
	CFC–12	29.0
	CFC–114	7.0
Schering Corporation	CFC–11	301.0
	CFC–12	747.0
	CFC–114	0.0
Sciarra Laboratories, Inc.	CFC–11	0.2
	CFC–12	0.7
	CFC–114	0.4
(ii) Cleaning, Bonding and Surface Activation Applications for the Space Shuttle Rockets and Titan Rockets		
National Aeronautics and Space Administration (NASA)/Thiokol Rocket	Methyl Chloroform	56.7
United States Air Force/Titan Rocket	Methyl Chloroform	3.4

The table above reflects FDA's determination of the quantities CFCs that are necessary for calendar year 2000 and breaks down the amount of CFC by molecule. However, in developing today's action, EPA has decided to allocate essential-use allowances in aggregate amounts in accordance with Decision X/6 of the Parties to the Montreal Protocol. Paragraph 2 of Decision X/6 states that the ''levels of production and consumption necessary to satisfy essential uses of CFC–11, CFC–12, CFC–113, and CFC–114, for metered-dose inhalers for asthma and chronic obstructive pulmonary diseases * * * are authorized as specified in annex I to the report of the Tenth Meeting of the Parties.'' Paragraph 5 of Decision X/6 goes on to say that ''the quantities approved under paragraph 2 above and all future approvals are for total CFC volumes with flexibility between CFCs within each group.'' EPA has determined that allocating essential-use allowances for CFCs for the manufacture of metered-dose inhalers in the aggregate instead of on a compound-by-compound basis will add flexibility for protecting patient health by allowing companies to better meet market demand for MDIs. Because CFC–11, CFC–12 and CFC–114 all have an ozone depleting potential of 1.0, allocating these substances in the aggregate will not cause any additional damage to the stratospheric ozone layer.

The International Pharmaceutical Aerosol Consortium (IPAC) consolidated the essential use exemption requests of its member companies for administrative convenience. EPA will separately allocate the essential-use allowances that FDA has determined to be ''necessary'' to each of IPAC's member companies by means of a confidential letter.

Although the Montreal Protocol does allow for a global essential use exemption for small quantities of high quality Class I ODS for use in laboratory applications, the CAA does not contain an explicit exemption for this use. Therefore, import and production of CFCs and carbon tetrachloride for use in laboratory and analytical applications may no longer be available for this use. Today's action allocates CFCs for use in metered dose inhalers and methyl chloroform for use in the Space Shuttle and the Titan Rocket. Laboratory essential uses will not be addressed in today's rulemaking. A separate final rule addressing laboratory essential uses will be published at a later date.

What Reporting Requirements Relate to the Essential Uses of Ozone Depleting Substances?

Any person obtaining class I controlled substances after the phaseout under the essential use exemptions in today's action is subject to all the restrictions and requirements in other sections of 40 CFR part 82, subpart A. Holders of essential-use allowances or persons obtaining class I controlled substances under the essential-use exemptions must comply with the record keeping and reporting requirements in 40 CFR 82.13.

IV. Response to Comments

EPA received comments from six organizations in response to the proposed rule. Three of these organizations commented on various aspects of the allocation of ODSs for medical devices, and three discussed the possibility of the lack of essential use exemptions for laboratory essential uses. Because a final rule addressing laboratory essential uses will be published separately at a later date, the only comments discussed in this section are those regarding the essential use allocation for medical devices.

One commenter stated that EPA may only authorize production and/or importation of CFCs for an MDI if EPA determines that there is no safe and effective alternative *propellant* to the CFCs used in the MDI. The commentor asserts that FDA approval of a product under the FDCA means that the alternative propellant in that product is safe and effective for purposes of the CAA. The effect of this interpretation would be limited, according to the commentor, because ''it is only the CFC-containing product that contains the same active moiety and same labeled indications that no longer qualifies as a 'medical device.' ''

We do not share the commentor's interpretation of the statutory language.

The first prong of the definition of ''medical device'' reads as follows: ''The term ''medical device'' means any device * * *, diagnostic product, drug * * *, and drug delivery system * * * if such device, product, drug, or drug delivery system utilizes a class I or class II substance for which no safe and effective alternative has been developed, and where necessary, approved by the Commissioner.'' According to the commentor, the phrase ''for which no safe and effective alternative has been developed'' modifies ''class I or class II substance,'' and not ''device, product, drug, or drug delivery system.'' The difficulty with the commenter's interpretation is that FDA does not approve MDI propellants separately from drug products. Thus, it is impossible for FDA to approve an alternative to the class I or class II substance (i.e., the propellant) alone since FDA only approves MDIs under an ANDA or NDA as a whole unit and not by approving each of its components. For this reason, even if we were to agree with the commentor that the statutory language was clear on its face, this would be a situation where the literal meaning of the statutory text would produce absurd results. We believe that the overall purpose of the CAA language regarding medical devices is to ensure that EPA's mission of environmental protection does not conflict with FDA's mission of protecting the public health. Consistent with this purpose, we believe that in drafting this prong of the definition, Congress was focusing on the availability of alternative medical treatment for patients who rely on CFC MDIs. We are not the appropriate agency to decide whether such alternative medical treatment is available. We do not believe that Congress intended EPA to make decisions involving medical judgment. On such questions, we defer to FDA. Because FDA has not identified any ''safe and effective alternative,'' as the phrase is used in the CAA, for any CFC MDI, the first prong of the definition of ''medical device'' has not affected today's allocation.

One commentor asserted that ''the CAA contemplates a product-by-product determination of essentiality at the time a particular product is approved,'' and that this principle applies to generic drugs as well as brand-name drugs. We do not believe that the statutory language requires each product's essentiality to be determined in a vacuum, as if no other products of that type existed. The definition of medical device states that a device, product, drug, or drug delivery system is a medical device if the first prong of the definition is satisfied 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.'' This language does not prevent FDA from grouping together particular types of products containing the same active moiety and determining that all products using a given active moiety are essential. Our understanding is that FDA has always added uses to its essential use list through notice and comment rulemaking. Because FDA's list of essential uses is determined by active moiety and makes no reference as to whether a drug product is generic or branded, we believe all MDIs for which we are allocating CFCs are covered by 21 CFR 2.125, regardless of whether they were or will be approved under an NDA or ANDA.

This commentor also objects to EPA's use of FDA's pre-1990 determinations of essentiality in deciding whether an MDI qualifies as a ''medical device'' for purposes of the 1990 CAA Amendments. The commentor states that EPA cannot allocate essential use allowances for particular MDIs until FDA finalizes the proposed revisions to its essential use regulations or engages in a separate rulemaking to determine whether those MDIs are essential.

While we are aware that FDA is currently engaged in rulemaking to revise its essential use regulations, we are relying on FDA's current essential use list at 21 CFR 2.125 for purposes of today's action. That list contains all of FDA's determinations regarding ''essentiality'' to date. The statute does not specify a particular time at which FDA must make such a determination or invalidate determinations made prior to the date of the 1990 CAA Amendments. Additionally, the 1990 Amendments to the Clean Air Act use language consistent with FDA's regulations at 21 CFR 2.125. We presume that Congress was aware of FDA's regulations when it passed the 1990 Amendments to the CAA. Therefore, we believe that the current essential use list remains valid. If FDA revises its regulations, we will take the revised list into account in future allocation decisions.

We received several comments on the meaning of the word ''approved'' in section 601(8)(B). In the preamble to the proposed rule, we stated that EPA and FDA were discussing how best to interpret this term, and that there were at least two possible interpretations. One such interpretation was that FDA had to approve the specific product under the FDCA. The second interpretation was that FDA had to have approved either that product or another product that contained the same active moiety. Several commentors stated that the second interpretation would be contrary to the plain meaning of the statute.

Section 601(8)(B) refers to approval as occurring ''after notice and opportunity for comment.'' FDA has informed us that approvals of drug products under the FDCA are issued without notice and comment. For this reason, FDA has concluded that in using the word ''approved,'' Congress cannot have been referring to approval of the drug product under the FDCA. We agree with this conclusion. We also note that the statutory language refers to actions taken by FDA, *in consultation with EPA.* FDA does not consult with EPA prior to approving drug products under the FDCA. Furthermore, FDA points out that it has provided notice and opportunity for comment prior to adding categories of drug products to the essential use list in 40 CFR 2.125. (FDA has also informally consulted with EPA in the course of such actions.) Therefore, FDA interprets the phrase ''approved and determined to be essential'' as referring to FDA's action in approving the use of CFCs in MDIs containing a particular active moiety as an essential use. As a result, FDA regards all MDIs containing an active moiety that appears on its essential use list as ''approved'' for purposes of 601(8)(B). According to this interpretation, an MDI that has not yet received approval of its ANDA or NDA under the FDCA is considered to be approved as an essential use if it contains an active moiety that appears on the essential use list.

Two commentors stated that section 601(8)(B) requires FDA approval of the ''medical device'' itself and that an active moiety cannot be a ''medical device''. We would like to clarify that the term ''device'' and the phrase ''medical device'' have two separate and distinct definitions. ''Medical device'' is defined under 601(8) of the CAA. ''Device'' is defined under the FDCA. Furthermore, we are not stating that the active moiety in an MDI is a ''medical device'' under the CAA. Rather, FDA and EPA are interpreting section 601(8)(B) to allow MDIs to be ''approved and determined to be essential'' by active moiety. That is, if FDA, in consultation with EPA, has listed MDIs containing a particular active moiety as essential, then a separate determination is not necessary for each MDI that

contains that active moiety. FDA has listed MDIs with reference to the active moiety. Therefore, an MDI that contains an active moiety that appears on FDA's essential use list has been ''approved and determined to be essential.''

One commentor stated that according to principles of statutory construction, the term ''approved'' should be interpreted the same way in section 601(8)(A) and section 601(8)(B). We believe that the term ''approved'' must be interpreted in light of the surrounding language in each instance. Section 601(8)(B) requires notice-and-comment rulemaking and refers to action by FDA, in consultation with EPA. Since approval under the FDCA involves unilateral action by FDA without notice-and-comment rulemaking, it is reasonable to conclude that section 601(8)(B) does not refer to approval of an NDA or ANDA under the FDCA. Instead, we interpret the phrase ''approved and determined to be essential'' as referring to any MDI that contains an active moiety appearing on FDA's essential use list. This interpretation is consistent with the surrounding language, as FDA adds uses to its list through notice-and-comment rulemaking, and EPA has a clear interest in being consulted regarding the listing of essential uses of ODS.

In regard to section 601(8)(A), we interpret this section as requiring a determination by FDA that there is a ''safe and effective alternative'' to a CFC MDI. Approval under the FDCA may be a prerequisite to such a determination. (We note that the statutory language calls for approval ''where necessary.'') Because section 601(8)(A) does not refer to notice and comment rulemaking or consultation with EPA, it is reasonable to interpret the reference to ''approval'' as a reference to approval under the FDCA. However, neither EPA nor FDA views FDA approval of a non-CFC product under the FDCA as constituting a determination that the product is a ''safe and effective alternative'' to any CFC MDI. That determination would require a separate analysis. FDA has described some of the factors that would enter into such an analysis in the preamble to its September 1, 1999 notice of proposed rulemaking on essential use determinations (64 FR 47735), and we refer the reader to that notice for further details.

This commentor also stated that the term ''approved'' as used in section 601(8)(B) should be interpreted as it is interpreted under the FDCA, to refer to the entire drug product rather than simply the active ingredients. For the reasons stated above, we have concluded that the word ''approved'' in section 601(8)(B) does not refer to approval under the FDCA.

One commentor stated that EPA had not meaningfully addressed the requirements of section 604(d)(2) of the CAA, the exception for medical devices. This commentor stated that EPA must provide information on ''current market demand for the use of CFCs in particular MDIs, what quantities of CFCs were requested by particular companies in their annual applications for each particular active moiety and how the essential use allowances are ''necessary'' or ''limited'', and how the applicant met its burden of demonstrating that it qualifies for CFCs under the essential use criteria set out in the Act.''

Section 604(d)(2) of the CAA states that ''the Administrator, after notice and opportunity for public comment, shall, to the extent such action is consistent with the Montreal Protocol, authorize the production of limited quantities of class I substances solely for use in medical devices if such authorization is determined by the Commissioner, in consultation with the Administrator, to be necessary for use in medical devices.'' As described in Section II of this preamble, EPA and FDA have consulted on whether the limited quantities contained in the proposed rule were ''necessary'' for use in medical devices, and FDA has determined that 2737.3 tons of the proposed amount are ''necessary.'' Accordingly, in this interim final rule, EPA is allocating 2737.3 tons for use in medical devices.

With regard to the commentor's request for information, the letter from FDA states the following: ''. . . we [FDA] have examine the table in your [EPA] proposed rule that lists the essential use amounts requested by sponsors for production of medical devices (64 FR 59143, Table 1). We have also examined the information you obtained from individual sponsors regarding their intended use of CFCs in specific products. We compared this information to the information filed with us by sponsors in their annual reports.'' FDA goes on to say ''In listing the amounts we believe to be necessary for use in medical devices, we referred to historical use and have included an additional amount to allow for overage, for waste during manufacturing, for uncertainties in the supply chain of CFCs since they are no longer produced in the United States, for changes in future market shares of specific products, as well as for unforeseen circumstances in the market. We also provided additional amounts based on our knowledge of certain manufacturing problems. In addition, we eliminated any double-counting we found and eliminated allocations for uses not considered essential by the parties to the Montreal Protocol, even if those uses are currently listed in our regulation at 21 CFR 2.125(e).'' FDA also noted that they accounted for CFCs for use in the production of MDIs that would ultimately be exported to Canada. It should be noted that much of the data that FDA used in their analysis were confidential business information and cannot be shared publicly. These confidential data included each applicant's response to EPA's request for information on the quantity of each CFC to be used in the manufacture of specific products in calendar year 2000, EPA's historical data on yearly import and actual use of CFCs for each company, and information filed with FDA by drug sponsors in their annual reports.

The commentor further stated that in order to achieve the congressional objective of reducing and eliminating production and use of ODS ''as expeditiously as possible,'' ''EPA and FDA must conclude that new MDIs are not 'necessary' where FDA has approved or issued an 'apposable' letter for a CFC-free alternative involving the same active moiety and overlapping labeling as that in the CFC-containing MDI.'' The commentor also states that if EPA nonetheless finds that CFCs are necessary for these MDIs, EPA must limit the quantities allocated to those that are necessary until the CFC-free alternative is approved. The commentor goes on to describe this stance as a ''policy.''

Under section 604(d)(2) of the CAA, FDA (in consultation with EPA) determines whether production or import of CFCs for MDIs is necessary. EPA does not independently make such a determination, as the comment appears to suggest. We defer to FDA on the wisdom of adopting the policy urged by the commentor. The commentor has not demonstrated that this policy is compelled by the statutory language. For purposes of today's action, we are relying on FDA's determination that the quantities allocated in the final rule are ''necessary.''

One commenter stated that EPA must ensure that its allocation is consistent with the decisions and recommendations of the Parties to the Montreal Protocol. The commenter refers to two existing decisions: Decision IV/25, which provides criteria for assessing essential uses for purposes

of the Protocol's control measures, and Decision VIII/10, which addresses the transition away from CFC-based MDIs.

Decision IV/25 contemplates that Parties nominating essential uses will apply the stated criteria at the time of nomination, and that the Protocol's Technology and Economic Assessment Panel will apply these criteria in developing its recommendations on whether the Parties should approve the nominated uses and quantities at their yearly meeting. Thus, these criteria drive the essential use process at the international level. The uses to which we are allocating CFCs in today's action were approved at the Tenth Meeting of the Parties, after nomination by the U.S. and evaluation by the Technology and Economic Assessment Panel. Therefore, we believe today's allocation is consistent with the Protocol. In addition, the commenter has not identified any respect in which these uses fail to meet the criteria in Decision IV/25.

Decision VIII/10 describes a variety of actions that Parties are to request MDI companies to undertake. For example, Parties are to ''request companies applying for MDI essential-use exemptions to demonstrate that they are undertaking individual or collaborative industry efforts, in consultation with the medical community, to educate health-care professionals and patients about other treatment options and the transition to non-CFC alternatives.'' (Decision VIII/10(2)) The TEAP Handbook on Essential Use Nominations was revised in 1997 to incorporate requests relevant to Decision VIII/10. For example, question B.2. of the form entitled ''Nomination of the Aerosol Metered Dose Inhaler (MDI) as an Essential Use,'' in Appendix D of the TEAP Handbook on Essential Use Nominations, requests applicants to ''List and describe in detail the education efforts, individual and/or collaborative, being undertaken to advise patients and health care professionals about treatment options and the transition to non-CFC alternatives.'' EPA requests companies applying for MDI essential-use exemptions to submit the information specified in the TEAP Handbook, including the information relevant to Decision VIII/10 . Nevertheless, we do not view Decision VIII/10 as imposing barriers to allocation. The Decision does not attach any consequences to the company's failure to comply with any of the requests. The commenter incorrectly describes Decision VIII/10 as ''requiring'' manufacturers of CFC MDIs to take the specified actions. By its own terms, the Decision simply states that Parties ''will request'' companies to take these actions.

One commenter stated that under the CAA EPA cannot allocate CFCs to Medisol Laboratories for use in their generic albuterol MDI because this product does not fall within the definition of a ''medical device'' under the statute. For reasons stated above, EPA considers the generic albuterol MDI to be a medical device as defined by the statute and thus eligible to receive essential use allowances. While we are aware that FDA has approved a CFC-free albuterol product, FDA has not determined that this product is a ''safe and effective alternative'' to the Medisol generic albuterol MDI. In addition, albuterol is an adrenergic bronchodilator. FDA continues to regard the use of CFCs in ''[m]etered-dose adrenergic bronchodilator human drugs for oral inhalation'' as essential (21 CFR 2.125(e)(3)). Because FDA's list of essential uses makes no reference as to whether a drug product is generic or branded, we believe all MDIs for which we are allocating CFCs are covered under 21 CFR 2.125 regardless of whether they were or will be approved under an NDA or ANDA. Therefore, we believe that CFC albuterol MDIs are ''medical devices.'' Finally, we have based our allocation of 49 tons of CFCs to Medisol on FDA's determination that this quantity is ''necessary'' under CAA section 604(d)(2).

One commenter stated that Sciarra's application for essential use allowances for production of albuterol, epinephrine hydrochloride, ipratropium bromide, triamcinalone acetonide, beclomethasone dipropionate, and cromolyn sodium MDIs should be denied because these products do not satisfy many, if not all of the requirements set by the CAA. According to the commenter, an albuterol MDI should not qualify as a ''medical device'' under the CAA because there is a ''safe and effective alternative propellant'' (HFC–134a), that is, a safe and effective alternative to the CFCs used in albuterol MDIs. Additionally, the commenter stated that FDA has not determined that the generic products listed above are essential after notice and opportunity for public comment. The commenter also noted that FDA has issued apposable letters for CFC-free versions of all the above moieties except epinephrine and ipratripium, and concluded that even if these products qualify as ''medical devices,'' the allocation of CFCs is not ''necessary.'' Additionally, the commenter stated that Sciarra's application provided inadequate information in its response to the Protocol criteria. Specifically, Sciarra did not provide information about the availability of alternatives to CFC MDIs or information on its plans for implementation of these alternatives. The commenter did note that Sciarra had stated that it would develop its own non-CFC products after receiving approval for its CFC-containing products.

As stated before, while FDA has approved a CFC-free albuterol product, FDA has not determined that this product is a ''safe and effective alternative'' to any other albuterol product. In addition, albuterol is an adrenergic bronchodilator. FDA continues to regard the use of CFCs in ''[m]etered-dose adrenergic bronchodilator human drugs for oral inhalation'' as essential (21 CFR 2.125(e)(3)). Therefore, we believe that CFC albuterol MDIs are ''medical devices.'' Our understanding is that FDA has always added uses to its essential use list through notice and comment rulemaking. Because FDA's list of essential uses makes no reference as to whether a drug product is generic or branded, we believe all MDIs for which we are allocating CFCs are covered under 21 CFR 2.125 regardless of whether they were or will be approved under an NDA or ANDA. In Sciarra's response to the CAA section 114 letter that EPA sent to MDI manufacturers on October 13, 1999, Sciarra provided a refined list of moieties for the MDIs for which it is requesting CFCs. The use of any of these moieties in an MDI is essential under 21 CFR 2.125(e). With the regard to the issue of whether CFCs are ''necessary'' for the Sciarra MDIs, we are relying on FDA's determination. FDA, in its analysis of the amount of CFCs necessary for the production of MDIs, determined that much of the quantity we had proposed to allocate to Sciarra was not ''necessary'' because at present, Sciarra does not have any currently approved CFC MDIs. The essential use allocation for Sciarra was reduced accordingly in this interim final rule.

The TEAP Handbook contains several questions relating to the availability of alternatives. As we noted earlier, many of the questions in the current TEAP Handbook derive from Decision VIII/10. This Decision directs the Parties to request certain information from companies applying for MDI essential-use exemptions. However, it does not attach specific consequences to a company's failure to provide information, nor does it state what constitutes an adequate response.

One commenter stated that the application for CFCs from Schering should be denied only if EPA also denies CFC applications for albuterol MDIs for all other companies marketing such products. The commenter identified Schering as the company that markets the non-CFC albuterol MDI. For the reasons stated above, EPA is allocating CFCs to manufacturers of CFC albuterol MDIs, including Schering.

One commenter stated that the public version of the application for the International Pharmaceutical Aerosol Consortium (IPAC) did not provide information about the specific products that would be manufactured using the essential use allowances. The commenter noted that Medeva Americas is one of the companies identified in the IPAC proposal, and stated that this company markets a generic CFC albuterol MDI. The commenter further stated that another IPAC company, Glaxo Wellcome, markets a CFC albuterol MDI. According to the commenter, neither of these companies should receive CFC allocations for these products.

IPAC completed the application for essential use allowances in accordance with the TEAP Handbook. EPA requested information about the specific products for which the allowances would be used from IPAC's member companies in a letter issued pursuant to section 114 of the CAA on October 13, 1999. The responses to these letters are considered confidential business information and are therefore not available in the public docket. As stated earlier FDA used this information in its analysis of what quantities of CFCs are necessary for the production of medical devices as defined in the Act. Each of the products for which FDA determined a quantity of CFCs to be necessary is ''essential'' under 21 CFR 2.125(e). Since the commenter specifically mentions albuterol, we note again that albuterol is an adrenergic bronchodilator. FDA continues to regard the use of CFCs in ''[m]etered-dose adrenergic bronchodilator human drugs for oral inhalation'' as essential (21 CFR 2.125(e)(3)). Our understanding is that FDA has always added uses to its essential use list through notice and comment rulemaking. Because FDA's list of essential uses makes no reference as to whether a drug product is generic or branded, we believe all MDIs for which we are allocating CFCs are covered under 21 CFR 2.125 regardless of whether they were or will be approved under an NDA or ANDA. Furthermore, as stated before, while FDA has approved a CFC-free albuterol product, FDA has not determined that this product is a ''safe and effective alternative'' to any other albuterol product. Therefore, we believe that CFC albuterol MDIs are ''medical devices.''

One commenter stated that EPA determines the safety and efficacy of alternatives to CFCs under the Significant New Alternatives Policy (SNAP) program (section 612 of the CAA). The commenter further stated that EPA relies upon FDA's approval of medical products containing alternative propellants as a determination that the alternative propellant has no adverse human health effects. The commenter concluded that ''when FDA approves a product containing an alternative propellant as safe and effective under the FDCA, EPA concludes that the non-CFC propellant in that product is safe and effective for the purposes of the CAA.''

Under section 612 of the CAA, EPA determines whether substitutes for ozone-depleting substances may present adverse effects to human health or the environment. In the SNAP rule published in the **Federal Register** on March 18, 1994 (59 FR 13044), EPA stated: ''Some medical devices * * * currently contain class I or class II compounds. The Agency has determined that such products are exempt from further review for human health effects under the SNAP program where FDA approval of such effects is required before a product can be introduced into commerce. EPA will rely in its SNAP determination on FDA's conclusions regarding health effects. The Agency believes this exemption is justified because of the higher burden of proof placed on submitters under the FDCA. However, the Agency will continue to evaluate all other environmental effects of the proposed substitute, and will consult with the FDA to determine the appropriate course of action.'' (59 FR 130660).

The quoted language simply indicates that EPA will conclude that a substitute does not present adverse health effects if FDA approves, under the FDCA, a product containing the substitute. It does not say that EPA will treat the product approval as a determination that the substitute is a ''safe and effective alternative'' to the ODS for purposes of section 601(8)(A). FDA approval of a CFC-free MDI under the FDCA does not constitute approval of the non-CFC propellant as safe and effective. Such approval relates to the product in its entirety, not to the propellant. Therefore, it would be inappropriate for the EPA to conclude from FDA's approval of a non-CFC MDI that the non-CFC propellant had been approved for use in MDIs generally. In listing acceptable alternatives under the SNAP program, EPA does not intend to preempt FDA's role in approving individual products or in deciding whether a particular product is a safe and effective alternative for another.

V. Administrative Requirements

A. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector.

Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Section 204 of the UMRA requires the Agency to develop a process to allow elected state, local, and tribal government officials to provide input in the development of any proposal containing a significant Federal intergovernmental mandate.

Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local, or tribal governments or the private sector. Because this rule imposes no enforceable duty on any State, local or tribal government it is not subject to the requirements of sections 202 and 205 of the UMRA. EPA has also determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments; therefore, EPA is not required to develop a plan with regard to small governments under section 203. Finally, because this rule does not contain a significant intergovernmental mandate, the Agency is not required to develop a process to obtain input from elected state, local, and tribal officials under section 204.

B. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether this regulatory action is ''significant'' and therefore subject to OMB review and the requirements of the Executive Order. The Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlement, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. It has been determined by OMB and EPA that this action is not a ''significant regulatory action'' under the terms of Executive Order 12866 and is therefore not subject to OMB review under the Executive Order.

C. Paperwork Reduction Act

This action does not add any information collection requirements or increase burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* The Office of Management and Budget (OMB) previously approved the information collection requirements contained in the final rule promulgated on May 10, 1995, and assigned OMB control number 2060–0170 (EPA ICR No. 1432.16).

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR Part 9 and 48 CFR Chapter 15.

D. Executive Order 13084: Consultation and Coordination With Indian Tribal Governments

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.'' Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

E. Regulatory Flexibility

After considering the economic impacts of today's final rule on small entities, EPA has determined that it is not necessary to prepare a regulatory flexibility analysis in connection with this final rule. EPA has also determined that this action will not have a significant economic impact on a substantial number of small entities. This rule does not have a significant impact on a substantial number of small entities. The only entities that are directly affected by this allocation are those to which CFCs and other ODSs are being allocated. There are only ten entities which are affected by this rulemaking (see table 1 above). This rule does not have an adverse economic impact on any entity because it grants exceptions to a pre-existing ban.

F. Applicability of Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045: ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997) applies to any rule that (1) is determined to be ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health and safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency. EPA interprets Executive Order 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5–501 of the Order has the potential to influence the regulation. This rule is not subject to Executive Order 13045 because it implements the phaseout schedule and exemptions established by Congress in Title VI of the Clean Air Act.

G. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Public Law No. 104–113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be

inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This rule does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

H. Executive Order 13132 (Federalism)

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Under Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

If EPA complies by consulting, Executive Order 13132 requires EPA to provide to the Office of Management and Budget (OMB), in a separately identified section of the preamble to the rule, a federalism summary impact statement (FSIS). The FSIS must include a description of the extent of EPA's prior consultation with State and local officials, a summary of the nature of their concerns and the agency's position supporting the need to issue the regulation, and a statement of the extent to which the concerns of State and local officials have been met. Also, when EPA transmits a draft final rule with federalism implications to OMB for review pursuant to Executive Order 12866, EPA must include a certification from the agency's Federalism Official stating that EPA has met the requirements of Executive Order 13132 in a meaningful and timely manner. This interim final rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. This interim final rule will affect only the ability of private entities and the national government to request production of controlled ozone-depleting substances. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

VI. Judicial Review

Under Section 307(b)(1) of the Act, EPA finds that these regulations are of national applicability. Accordingly, judicial review of this action is available only by the filing of a petition for review in the United States Court of Appeals for the District of Columbia Circuit within sixty days of publication of this action in the **Federal Register**. Under Section 307(b)(2), the requirements of this rule may not be challenged later in judicial proceedings brought to enforce those requirements.

VII. Congressional Review

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 808 allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency makes a good cause finding that notice and public procedure is impracticable, unnecessary or contrary to the public interest. This determination must be supported by a brief statement. 5 U.S.C. 808(2). As stated previously, EPA has made such a good cause finding, including the reasons therefor, and established an effective date of January 6, 2000. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 82

Environmental protection, Administrative practice and procedure, Air pollution control, Chemicals, Chlorofluorocarbons, Exports, Hydrochlorofluorocarbons, Imports, Ozone layer, Reporting and recordkeeping requirements.

Dated: December 30, 1999.

Carol M. Browner,

Administrator.

40 CFR Part 82 is amended as follows:

PART 82—PROTECTION OF STRATOSPHERIC OZONE

1. The authority citation for part 82 continues to read as follows:

Authority: 42 U.S.C. 7414, 7601, 7671–7671q.

Subpart A—Production and Consumption Controls

2. Section 82.4(t)(2) is amended by revising the table to read as follows:

§ 82.4 Prohibitions.

* * * * * *

(t) * * *

(2) * * *

TABLE I.—ESSENTIAL USE ALLOCATION FOR CALENDAR YEAR 2000

Company	Chemical	Quantity (metric tons)
(i) Metered Dose Inhalers for Treatment of Asthma and Chronic Obstructive Pulmonary Disease (in metric tons)		
International Pharmaceutical Aerosol Consortium (IPAC)—Medeva Americas, Inc., Boehringer Ingelheim Pharmaceuticals, Glaxo Wellcome, Rhone-Poulenc Rorer, 3M.	CFC–11 or CFC–12 or CFC–114	1639.0
Medisol Laboratories, Inc.	CFC–11 or CFC–12 or CFC–114	49.0
Schering Corporation	CFC–11 or CFC–12 or CFC–114	1048.0
Sciarra Laboratories, Inc.	CFC–11 or CFC–12 or CFC–114	1.3
(2)(ii) Cleaning, Bonding and Surface Activation Applications for the Space Shuttle Rockets and Titan Rockets		
National Aeronautics and Space Administration (NASA)/Thiokol Rocket	Methyl Chloroform	56.7
United States Air Force/Titan Rocket	Methyl Chloroform	3.4

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