40 CFR Parts 141 and 142

Environmental protection, Reporting and recordkeeping requirements, Water supply.

Dated: June 21, 2000.

J. Charles Fox,

Assistant Administrator for Water.

For the reasons set out in the preamble, 40 CFR part 9 is amended as follows:

1. The authority citation of part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.*, 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735; 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.*, 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

2. In § 9.1, the table is amended by removing ''142.10–142.13'' and adding the new entries in numerical order under the indicated heading to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

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40 CFR citation	OMB control No.
* * * * *	
National Primary Drinking Water Regulations Implementation	
* * * * *	
142.10	2040–0090
142.11(a)(1)–(a)(5)	2040–0090
142.11(a)(6)	2040–0915
142.11(a)(7)	2040–0090
142.12	2040–0090
142.13	2040–0090
* * * * *	

[FR Doc. 00–16368 Filed 6–29–00; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[FRL–6726–5]

RIN 2060–A173

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: Final rule.

SUMMARY: With this action, EPA is allocating essential-use allowances for calendar year 2000 for stratospheric 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 class I ODS 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 phase-out of production and import of these substances.

EFFECTIVE DATE: This action is effective June 30, 2000.

ADDRESSES: Materials relevant to this rulemaking are contained in Docket No. A–93–39. 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 Essential Use Process

The Montreal Protocol on Substances that Deplete the Ozone Layer (Protocol) is the international agreement to reduce and eventually eliminate production and consumption of all stratospheric ozone depleting substances. This is accomplished through adherence to phase-out schedules for the production and consumption of specific ODS including chlorofluorocarbons (CFCs), halons, carbon tetrachloride, methyl chloroform, hydrochlorofluorocarbons, and methyl bromide. As of January 1996, production and import of class I ODSs were phased out in all developed countries, including the United States. However, the Protocol and the Clean Air Act (CAA or Act) provide exemptions which allow for the continued import and/or production of class I ODS for specific uses. Under the Montreal Protocol, exemptions are granted for uses that are determined by the Parties to be ''essential.'' Decision IV/25, taken in 1992, established criteria for determining whether a specific use should be approved as essential, and set forth the international process for making determinations of essentiality. The CAA provides for specific exempted uses for which class I ODSs may continue to be produced and imported.

Once the U.S. nomination for essential use allowances is approved by the Parties, the U.S. EPA allocates essential use allowances to each essential use applicant in accordance with the CAA. For the year 2000 and beyond, the CAA requires EPA to formally consult with the Food and Drug Administration (FDA) on the amount of CFCs that are necessary for the production of medical devices. On January 6, 2000, EPA issued an interim final rule (IFR) allocating essential use allowances for use in metered dose asthma inhalers (MDIs) and in the Space Shuttle and Titan Rocket (65 FR 716). Today's action allocates essential use allowances for use in medical devices and reflects the final determination of the amount of CFCs that are necessary for use in medical devices for calendar year 2000. This final rule also allocates

methyl chloroform for use in the Space Shuttle and Titan Rocket solid rocket motor assemblies.

What Was the International Procedure for Approving Essential Use Exemptions for the Year 2000?

The international process for nominating and approving essential use allocations for CFCs for use in medical devices for the year 2000 occurred in the same way as in prior years. The entities in Table I submitted applications requesting class I controlled substances for essential uses in response to a **Federal Register** notice in the Fall of 1998. Their applications requested exemptions for the production and import of specific quantities of certain class I controlled substances after the phase-out, and 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.'' EPA reviewed the applications and nominated these uses to the Protocol Secretariat for analysis by the Technical and Economic Assessment Panel (TEAP) and its Technical Options 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).

Overview of the Notice of Proposed Rulemaking and Interim Final Rule

The Notice of Proposed Rulemaking (NPRM) for allocating essential use allowances for the year 2000 was published on November 2, 1999 (64 FR 59141). In the NPRM, EPA proposed allocating CFCs for use in metered dose inhalers (MDIs) that meet the medical device definition in the Act, and methyl chloroform for use in the Space Shuttle and Titan Rocket. In the NPRM, EPA proposed to allocate the entire amount of CFCs for use in MDIs that was granted to the U.S. by the Parties to the Montreal Protocol, which was 3735 metric tons. However, EPA explained that because of additional requirements in the Clean Air Act that apply beginning in calendar year 2000, EPA needed to formally consult with FDA regarding the amount of CFCs that are necessary for use in medical devices for calendar year 2000 prior to issuing a final allocation. Following EPA's consultation with FDA, it was determined that a total of 2737 metric tons were necessary for production of MDIs for the year 2000. This allocation was reflected in the IFR published on January 6, 2000 (65 FR 716). By issuing the allocation as an interim final instead of a final rule, EPA ensured that there would be sufficient opportunity for all stakeholders to comment on the revised allocation while ensuring that CFCs were available for continued production of MDIs. Originally EPA planned to receive comments until February 7, 2000, however, in response to requests by stakeholders, EPA published a notice in the **Federal Register** on February 25, 2000 (65 FR 10025) extending the comment period on the IFR until March 27th, 2000.

EPA received a number of comments on the IFR published January 6, 2000 covering the following areas: the amount of CFCs allocated to specific companies, the process that EPA used in allocating essential use allowances for the year 2000, and various legal interpretations of the medical device exemption provided in the Act. This final rule revises the allocation of CFCs for use in medical devices to reflect a final determination of the amount of CFCs necessary for use in medical devices. EPA consulted with FDA in arriving at this final determination.

In the NPRM and the interim final rule, EPA 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 laboratory essential uses; these will be addressed in a separate final rule.

II. Allocation Process for Calendar Year 2000

As discussed in the NPRM and IFR, the domestic allocation process for calendar year 2000 differs from past allocations due to changes in the requirements under the CAA. Prior to the year 2000, EPA allocated essential use exemptions under the original phase-out schedule contained in section 604 of the Act, and had the flexibility to create exemptions to the regulatory phase-out, where such exemptions had been approved under the Montreal Protocol. Thus, before the year 2000, EPA was able to authorize production and import of ODSs 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 did not exceed the amount permitted by the Act.

Once the phase-out date for a particular substance has passed (as it has for CFCs), EPA must implement exemptions for essential uses of these chemicals as specified under the Act in section 604(d).

What Is the Relevant Exemption to the Phase-Out Provided for in the Act?

In allocating CFCs for use in MDIs, EPA must implement the exception for medical devices found in section 604(d)(2) of the Act. This exception states that notwithstanding the phase-out, EPA shall, to the extent consistent with the Montreal Protocol, authorize production of limited quantities of class I ODSs for use in medical devices, if FDA, in consultation with EPA, determines that such production is necessary.

How Does EPA Interpret the Definition of ''Medical Device'' as Specified in the 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 categories of CFC-containing medical devices, as that term is used in the CAA, 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 fall within one of these categories. 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.'' EPA and FDA determined that in light of the surrounding language, this phrase refers 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. Since approval of an NDA or ANDA under the Food, Drug, and Cosmetic Act (FDCA) involves unilateral action by FDA without notice-and-comment rulemaking or consultation with EPA, it is reasonable to conclude that section 601(8)(B) does not refer to approval of an NDA or ANDA under the FDCA. Therefore, FDA and EPA read section 601(8)(B) to refer to FDA's approval of an essential use which does require notice-and comment rulemaking in consultation with EPA. This means that an MDI is ''approved and determined to be essential'' if the MDI is included within the list of categories of CFC–MDIs on FDA's essential use list. All of the MDIs for which we are allocating CFCs today meet this qualification.

How Did EPA Consult With FDA on the Amount of CFCs Necessary for Use in Medical Devices?

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.

The 1997 TEAP Handbook on Essential Use Nomination (Handbook), the guidance document for essential use exemption applications at the international level, does not request information regarding specific products for which the CFCs will be used. Therefore, EPA sought more detailed information including which drug products would be produced using CFCs allocated in calendar year 2000. EPA sent out letters to the essential use applicants for medical devices, requesting this additional information under section 114 of the Act (separate letters were sent to the International Pharmaceutical Aerosol Consortium (IPAC) member companies). 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 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 20, 1999, stated that 2737 metric tons of CFCs were necessary for use in medical devices for the year 2000, in contrast to the 3735 metric tons proposed to be allocated in the November 2, 1999 NPRM (64 FR 59141). A total of 2737 metric tons was subsequently allocated in the January 6, 2000 IFR (65 FR 716).

The rationale underlying the FDA determination was provided in Dr. Henney's letter to EPA dated December 20, 1999. ''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.

Three companies commented that they did not receive sufficient CFC allocations in the IFR for the production of MDIs to meet their needs for the year 2000. In lieu of specific written comments, one company requested a meeting with EPA and FDA. A summary of the meeting is posted in docket # A–93–39. Based on the information provided by this company at the meeting, FDA issued a letter to EPA, dated March 6, 2000, in which it stated the factors that had led it to increase the amount determined to be ''necessary'' (See docket # A–93–39). Relevant factors included new information about this company's manufacturing process, and the company's ''contractual obligations to produce product necessary for patient health on behalf of another company.''

In response to the other two companies who commented that additional CFCs were necessary, EPA and FDA requested that they provide the following information: the number of units produced in 1999, the number of units produced in the first quarter of 2000, the total number of units anticipated to be produced in 2000, the target fill weight per unit, total CFC to be contained in the product for 2000, the additional amount necessary for production of each product, and the total amount of CFCs per product line for the year 2000.

One company sent EPA the additional information, which was then shared with FDA. FDA noted some discrepancies between the numbers that were reported to EPA and those that were reported in that company's annual report to FDA. The company sent EPA and FDA additional clarification after which FDA re-assessed their determination on the amount of CFCs necessary for the year 2000. In their letter dated May 5, 2000 (see docket # A–93–39), FDA states that the company does in fact require an additional amount for the production of MDIs due

to greater than anticipated market growth for their products.

For the third company that commented that it did not receive sufficient CFCs in the IFR, representatives from EPA and FDA participated in a conference call with representatives from the company on May 22, 2000 where the company shared the information EPA had requested pertaining to their past MDI production and future needs with EPA and FDA verbally. FDA and EPA reviewed the information, taking into account the following factors enumerated in the December 20, 1999 letter to EPA. These factors include: historical use, the additional amount necessary for waste and overage during manufacturing, uncertainties in the supply chain of CFCs, changes in future market shares of specific products, and unforeseen circumstances in the market. Based on this review, EPA and FDA agreed that the allocation published in the IFR is sufficient to meet the needs projected for this company for the year 2000. In their letter dated June 13, 2000, FDA determined that an additional amount is not necessary for the production of their product.

In accordance with the determinations made by FDA in consultation with EPA, today's allocation on the amount of CFCs necessary for use in medical devices states that a total of 3136.3 metric tons are necessary for use in MDIs for calendar year 2000.

When Is This Rule Effective?

This final rule is effective on June 30, 2000. 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 phase-out 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 Final 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 the final determination of the amounts of CFCs that are necessary as specified under section 604(d)(2) of the Act. (Note: There is no change from the IFR to the year 2000 allocation for the Space Shuttle and Titan Rockets)

TABLE I.—ESSENTIAL USE ALLOCATION FOR CALENDAR YEAR 2000

Company	Chemical	Quantity (metric tons)
(i) Metered Dose Inhalers (for oral inhalation) 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, Aventis (formerly Rhone-Poulenc Rorer), 3M.	CFC–11 or CFC–12 or CFC–114.	2038.0
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
(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

EPA is adding a parenthetical to Table I clarifying that CFCs are granted for use in the production of MDIs for oral inhalation only. The Parties to the Montreal Protocol do not consider MDIs for nasal inhalation to be essential, and thus, under the CAA EPA cannot approve CFCs for this use or any other use not considered essential by the Parties to the Protocol. In turn, this means that companies may not use their essential use allocation to produce a product not considered essential by the Parties to the Protocol.

Why Is EPA No Longer Allocating CFCs on a Chemical by Chemical Basis?

As discussed in the January 6, 2000 IFR, EPA is allocating essential-use allowances in aggregate amounts in accordance with Decision X/6 of the Parties to the Montreal Protocol which states 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 CFCs for the manufacture of metered-dose inhalers in the aggregate instead of on a compound-by-compound basis will add flexibility to the regulatory scheme without causing any additional damage to the stratospheric ozone layer since CFC–11, CFC–12 and CFC–114 all have the same ozone depleting potential of 1.0.

How Will the IPAC Companies Be Informed of Their Individual Allocations?

The International Pharmaceutical Aerosol Consortium (IPAC) consolidated the essential use exemption requests of its member companies for administrative convenience. EPA has already separately allocated the essential-use allowances allocated in the IFR to each of IPAC's member companies by means of a confidential letter. EPA will send a revised allocation letter to those IPAC companies whose essential use allowances were changed in today's final rule.

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

Any person obtaining class I controlled substances after the phase-out 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.

How Will Essential Use Allowances for Medical Devices Be Allocated in the Year 2001?

EPA and FDA have worked together to plan a streamlined regulatory process for the year 2001 and beyond, summarized as follows:

1. In letters sent directly to MDI manufacturers under section 114 of the Act, EPA will request detailed information regarding CFC usage for the production of MDIs for prior years and projected needs for 2001.
2. EPA will share this information with FDA which will use this information in consultation with EPA as the basis for the determination of the amount of CFCs necessary for use in medical devices.
3. EPA will issue a proposed rule setting forth the proposed allocations of CFCs .
4. EPA plans to issue a final allocation rule by December, 2000 to provide adequate time for companies to replenish their supply of CFCs for MDI production in the year 2001. In the proposed allocation rule for the year 2001, to be published later this year, EPA will explain the process EPA will use for the essential use allocation in detail and request formal comment on it.

VI. Response to Comments

Three commenters stated that the amount of CFCs allocated to their companies in the January 6, 2000 IFR was too low; one company requested a meeting with the EPA and FDA to discuss their allocation. EPA and FDA met with this company on Thursday March 2, 2000. A summary of this meeting is posted in docket # A–93–39. FDA subsequently issued a supplemental letter to EPA, dated March 6, 2000, in which it stated the factors that had led it to increase the amount determined to be necessary. Relevant factors included new information about the company's manufacturing process and the company's ''contractual obligations to produce product necessary for patient health on behalf of another company.''

The second commenter requested additional essential use allowances with one portion to be used for production in the year 2000, and a second larger portion to be added to their year 2000 allocation for use in 2001. EPA and FDA determined that allocating additional amounts of CFCs to this company in calendar year 2000 for use in 2001 is not ''necessary'' as specified in section 604(d)(2), since EPA will soon be proposing to allocate CFCs to all essential use applicants with sufficient advance time for this commenter and other applicants to acquire additional amounts of CFCs and replenish their supply of CFCs for 2001. Therefore, in reassessing the amount that was necessary for the year 2000, EPA and FDA considered only the additional amount that was requested for use in the year 2000.

As described earlier in the preamble, EPA and FDA requested additional information from this company to substantiate its claim that additional CFCs for the year 2000 were necessary. Using this information, FDA in consultation with EPA, reassessed the amount of CFC necessary for the year 2000 and found that due to greater than anticipated market growth, this company does in fact require an additional amount of CFCs for use in medical devices. This determination was provided to EPA in a letter from Dr. Jane Henney dated May 5, 2000.

The third company commented that it should receive the amount of CFCs that EPA proposed to allocate in the NPRM since giving them a lesser amount would, in their view, imperil the public health by possibly reducing access to the lower cost asthma medicines this company might provide. In their comment, this company did not provide a statement of need based on the amount of CFC–MDIs they planned to produce for the year 2000. Therefore, EPA and FDA asked the company to provide EPA and FDA the same information as the other two companies had previously provided. Representatives from EPA, FDA, and this company held a conference call on May 22, 2000 to discuss their request (minutes are posted in docket # A–93–39). Based on review of the information that the company provided, FDA, in consultation with EPA, determined that the additional CFCs requested by this company were not ''necessary'' as defined in 604(d)(2) of the Act.

This same commenter stated that FDA had failed to take into account several critical issues including: (1) A reduced allowance will encourage manufacturers holding large allocations to withdraw their generic products from the marketplace in favor of more expensive, less effective brand name products; (2) the potential impact of the withdrawal of certain generic CFC–MDI products may result in a shortage of this drug, or an increased market share for more expensive brand name products; (3) if other producers of this product continue to have manufacturing problems, this could lead to a shortage of the product overall; (4) shrinking the availability of CFCs may impair FDA's ability to continue strong Good Manufacturing Practice (GMP) enforcement; and (5) the reduced allocation will negatively impact impoverished populations due to a possible shortage of generic CFC–MDIs.

EPA and FDA have concluded that the year 2000 essential use allocations already reflect the contingencies raised by the commenter. As stated previously, FDA, in consultation with EPA, determined allocations for individual companies based on historical CFC uses while accounting for uncertainties in manufacturing, including knowledge of certain manufacturing problems, uncertainties in the CFC supply chain, and changes in the MDI market. These allocations are calculated to insure that the full range of medical needs is met throughout the entire patient population.

Three commenters stated that EPA should not delay its consultation with FDA and should issue the final rulemaking for the calendar year 2001 allocation earlier in the year. One commenter explained that only after EPA grants a license for essential use volumes can an MDI manufacturer place CFC production orders, arrange shipping and make other administrative arrangements which can take up to 8 weeks before the CFCs arrive at the manufacturing facility. For this reason, this particular commenter suggested that EPA begin rulemaking in June, 2000 and issue essential use allowances for 2001 in September, 2000.

EPA has planned the year 2001 allocation process in close coordination with FDA, and is committed to providing essential use allowances for the year 2001 in as timely a manner as possible while fulfilling all of our obligations under the CAA. Although we plan to begin the rulemaking process in June, the nature of the rulemaking process and the extensive coordination necessary with FDA are such that issuing a final rule in September of this year may not be possible. As stated earlier however, the Agency does plan to issue a final rule allocating essential use allowances for the year 2001 by December, 2000.

Six commenters expressed surprise at the adjustment of the amount of CFCs allocated in the IFR for the year 2000, given the figures in the proposal. EPA proposed to allocate the amount of CFCs approved by the Parties to the Montreal Protocol for the year 2000. After

consultation with FDA, EPA ultimately allocated a lower amount. The process set out by the Protocol Parties requires national governments to nominate amounts required for essential uses well in advance of allocation. Making responsible projections of need years in advance of actual requirement presents difficulties to both companies requesting CFCs, and to national governments. In past years EPA allocated the entire amount approved by the Parties and left it up to companies to elect not to use their entire allocation if it was not necessary. With this system, often companies do not use their entire allocation. In fact, in the year 1999, EPA allocated 3665 metric tons of CFCs, while only 2644 metric tons were actually imported for this use. Similarly, in 1998, 4,363 tons of CFCs were allocated for use in medical devices although only 2,235.6 tons were actually imported or produced for MDIs in that year. Beginning in the year 2000, the CAA requires that EPA and FDA consider what amount is necessary before the allocation occurs. This year, because the Agencies were adjusting to the new process, they did not have time to finish their consultation prior to proposal. EPA and FDA nonetheless are confident that the numbers actually allocated better reflect medical need in the U.S. for the year 2000 than the numbers in either the NPRM or the IFR. Recognizing that the process is new, however, EPA elected to maximize opportunity for stakeholder input by publishing the revised determination as an IFR. This procedure proved valuable, since in the case of some commenters, further information substantiated a further refinement of the year 2000 allocation. As explained elsewhere in the preamble, EPA plans to issue the 2001 NPRM after consulting with FDA. This will result in a smoother process in which all stakeholders will be able to comment on the allocation, as well as the allocation process itself, after the NPRM is issued, obviating the need for an IFR.

Five commenters were concerned about the perceived lack of transparency in the EPA/FDA consultation over the amount of CFCs determined to be necessary for each company. These commenters felt that the FDA methodology, assumptions and other bases for determining the amounts necessary should have been subject to public review and comment, and that this lack of transparency in the allocation process should be remedied in the year 2001 and beyond. One commenter stated that EPA had provided inadequate notice in violation of the Administrative Procedures Act (APA), and that FDA's determination did not contain sufficient information to provide the commenter with an opportunity to provide meaningful comments on a number of significant issues. (We note that because this rulemaking was conducted under section 307(d) of the CAA, the relevant procedures are those contained in that section rather than in the APA.) One commenter stated that neither agency placed any non-confidential information on the record to support its determination, and that EPA relied excessively on the FDA determination on the amount of CFCs necessary. This commenter referred to section 307(d)(6)(C) of the CAA, which states that ''[t]he promulgated rule may not be based (in part or in whole) on any information or data which has not been placed in the docket as of the date of such promulgation.'' In the opinion of the commenter, contrary to Section 307(d)(6)(C), the IFR did not appear to have been based on ''information or data'' placed in the docket as of January 6, 2000. The commenter stated that the docket contains little if any information supporting EPA's authorization of CFC volumes, and no information supporting FDA's determination of the volume deemed ''necessary for use in medical devices''. As a result, the commenter concluded that interested parties could not comment in an informed manner on the final allocation.

EPA undertook a variety of measures to ensure that interested parties had an opportunity for meaningful comment on the allocation. The Agency published the initial allocation as an interim final rule, in order to encourage commenters to supply important information and, potentially, to affect the final allocation. In response to a commenter's request, EPA extended the comment period to ensure that commenters who wished to supply important information had adequate time to do so. In addition to reviewing written submissions, both EPA and FDA heard oral presentations from companies that disagreed with the interim final allocation. As described below, EPA attempted to place in the docket as much information as possible regarding the factual data on which the rule is based, and the methodology used in obtaining the data and analyzing the data. However, since much of the data on which the rule is based is treated as confidential business information, it has not been possible to include all relevant information in the public docket.

Dr. Jane Henney, Commissioner of the U.S. Food and Drug Administration, in her letter dated December 20, 1999, to Carol M. Browner, Administrator, U.S. EPA, set forth parameters used in determining the amount of CFCs necessary for MDIs in 2000. FDA provided further information about its revised determination in Dr. Henney's letters of March 6, 2000, May 5, 2000, and June 13, 2000 (these documents are filed in docket no. A–93–39). Composite data on the amount of CFCs actually used and the amount of CFCs allocated to the U.S. is compiled each year in a US CFC accounting framework available in the docket. The docket also contains EPA's letters issued on October 1, 1999, and October 13, 1999 pursuant to section 114 of the CAA requesting information from MDI manufacturers regarding the specific products they planned to produce using their essential use allowances and the amount of CFCs they would use for production in the year 2000. The responses to these letters contain confidential business information and thus are not available in the public docket. However, the types of information requested can be ascertained by examining the letters that EPA sent out to the MDI manufacturers. EPA provided FDA with the responses to these letters in the course of our consultation.

EPA agrees that the allocation in the future should be as transparent a process as possible while accounting for the confidential nature of the data employed to make the determination on the amount of CFCs necessary. Briefly, as a first step in assuring this transparency, EPA plans to describe fully in an upcoming NPRM the proposed process for future determinations, request comment on it, and carefully review all comments. EPA and FDA have planned a process which will allow the determination on the amount of CFCs necessary for each company for the year 2001 to occur in as open a manner as possible. At the beginning of the process, EPA will send out letters pursuant to section 114 of the Act requesting information from each potential essential use holder. These letters will request information such as the number of units of each product produced in previous years, the number of units produced in the first quarter of this year, the gross target fill weight per unit, the total CFC to be contained in the product for 2000, the number of units of each product anticipated to be produced in 2001, the additional amount of CFCs necessary for production, and the total amount of CFCs requested for each product in 2001. FDA will compare the information provided by the companies to information in annual reports submitted to FDA by the pharmaceutical

companies requesting an essential use allocation. In general, FDA and EPA will base the determination of necessary amounts and the allocation on this information. Thus, each company will know what information it has submitted as the basis for its own allocation, while the process will protect against disclosure of confidential business information to competitors. In addition, stakeholders will have an opportunity to comment on the proposed allocation prior to EPA issuing the final allocation for the year 2001.

One commenter proposed a reporting framework for companies to provide information on their CFC use for 1999 and to project their needs for the year 2001. EPA appreciates this input, and used the commenters' suggested reporting framework, along with other information, as a starting point for our discussions with FDA regarding the information we will request from companies as a basis for the year 2001 allocation. The reporting framework that was agreed upon for the year 2001 incorporates most of the information from this suggested framework, albeit in a slightly different format.

Several commenters took issue with EPA's interpretation of the CAA exemption for medical devices at section 601(8)(B) of the Act. Some stated that the term ''approved'' at 601(8)(B) should refer to a product under an approved NDA or ANDA, and not an approved active moiety. One commenter reasoned that EPA must interpret ''approved'' consistently in the definition of medical device, as words used in different parts of the same statute are intended to have the same meaning. Thus, since the commenter believed that section 601(8)(A) refers to approved drug products, the commenter argued that section 601(8)(B) must also. Another comment stated that EPA's reading of ''approved and determined to be essential'' as a single action renders the term ''approval'' meaningless, in violation of principles of statutory construction. One commenter also stated that EPA's reading of the word ''approved'' was inconsistent with the FDA September 1, 1999 proposed rule on the transition (64 FR 47735).[1]

EPA disagrees with these assessments since the word ''approved'' in section 601(8)(A) refers to an approved alternative and not an approved drug product. We refer to the explanation in the preamble to the FDA proposed rule which states ''although FDA approval does constitute a determination that a product is safe and effective on its own, this finding does not constitute a determination regarding whether one product is a medically acceptable alternative for another.'' Further, FDA's proposed rule does not require the drug product to be approved to receive CFCs. Rather, both the current regulations under 21 CFR 2.125(e) and the proposed rule by FDA to revise 2.125 contain a mechanism by which CFC use in an investigational drug may be considered essential.

Another commenter stated that Section 601(8) of the CAA requires that each drug product (*i.e.,* ''device, product, drug, or drug delivery system'') be approved and determined to be essential by FDA before it can qualify as a medical device under the CAA. The commenter goes on to state that under accepted rules of statutory construction, a list of specific items in a statute is intended to be finite, not illustrative, unless the statute expressly indicates otherwise. Thus, the commenter argues that because active moieties are not on this list, FDA can only approve and determine to be essential a device, product, drug, or drug delivery system. The commenter argues further that its interpretation is bolstered by the Food, Drug, and Cosmetic Act (FDCA), where ''approved drug'' has been held to mean the entire drug product and not merely the active ingredients in the drug product. However, the commenter does not recognize that the term ''drug,'' as used in the FDCA, can mean either ''drug product'' or ''active moiety.'' EPA, in consultation with FDA, believes that reading ''drug'' in this provision of the Act to mean ''active moiety'' most closely effectuates Congressional intent.

As stated in the preamble to the IFR, it is impossible to read the term ''approved'' in section 601(8)(B) as referring to approval of an New Drug Application (NDA) or Abbreviated New Drug Application (ANDA), considering the context in which that term is used. The passage states that the public must have notice and an opportunity for comment before the ''device, product, drug, or drug delivery system'' is ''approved and determined to be essential.'' FDA has informed us that approvals of drug products under the FDCA are issued without notice and comment. Furthermore, as noted in the preamble to the IFR, 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. We refer to the preamble for the IFR for a more detailed discussion of this issue. As the Supreme Court has noted: ''It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.'' *Davis* v. *Michigan Dept. of Treasury,* 109 S. Ct. 1504 (1989). Here, the context makes clear that ''approval'' cannot mean approval of an NDA or ANDA. Thus, the use of the terms ''approved'' and ''determined to be essential'' in the same sentence may simply be intended to clarify the nature of the action: *i.e.,*FDA, in consultation with EPA, makes a determination of essentiality and in so doing approves an exemption.

Three commenters stated that the CAA does not delegate to the FDA the authority to dictate the nomination quantity and allocation of class I substances for medical devices. Rather, the CAA requires only that the Administrator (of EPA) consult with the Commissioner (of FDA) as to whether the authorization of class I substances for medical devices is necessary. The commenters took issue with EPA's reading of the statute as directing the Commissioner of the FDA to determine the quantity of class I substances necessary for medical devices. The commenters believe that the CAA requires the FDA to make a yes/no decision regarding whether class I substances are necessary for use in an essential product, *i.e.,* technically necessary for the functioning of the MDI. According to the commenters, Title VI of the CAA requires FDA to determine whether a particular approved MDI using an ODS is '' essential,'' and whether no safe and effective alternatives exist. If these questions are answered affirmatively, then FDA must consult with EPA and determine whether CFCs are ''necessary'' for use in MDIs, *i.e.,* whether, as a technical matter, the device needs this chemical to operate properly. If so, then it is EPA's responsibility to determine ''after notice and opportunity for public comment'' what CFC volume should be authorized for use in those MDIs. Two commenters went on to state there is no indication that FDA is in a better position to make decisions on quantity, and that EPA has experience in evaluating the necessary amount of CFCs from the Agency's past review of companies' requests for class I substances for use in medical devices.

Section 604(d)(2) of the Act states the following: ''The Administrator, after notice and opportunity for public

[1] The FDA proposed rule on determinations of essentiality states that ''a food, drug, device, or cosmetic that is, consists in part of, or is contained in, an aerosol product or other pressurized dispenser that releases an ODS is an essential use of the ODS under the Clean Air Act if paragraph (e) of this section specifies the use of that product as essential. For drugs, including biologics and animal drugs, and for devices, an investigational application or an approved marketing application must be in effect, as applicable.''

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 [of FDA], in consultation with the Administrator [of EPA], to be necessary for use in medical devices'' (emphasis added). It is clear that the authorization in question may not be for an indefinite amount but must be for ''limited quantities.'' It is equally clear that the subject of the Commissioner's necessity determination is ''such authorization.'' Thus, if the latter part of the text quoted above were written in the active voice, it would say: ''if the Commissioner, in consultation with the Administrator, determines such authorization to be necessary for use in medical devices.'' We note that the expression ''such authorization'' refers back to the phrase ''authorize the production of limited quantities of class I substances solely for use in medical devices.'' Thus, the Commissioner of FDA must consider not only whether *any* production is necessary, but what *quantity* of production is necessary.

Further, although EPA does have some data on CFC usage (which is shared with FDA), medical experts at FDA are privy to confidential business information regarding annual sales and distribution of MDI products which gives them far more complete knowledge of the MDI market than EPA. Because of their access to additional information and the fact that their medical expertise is integral to making these decisions to protect the health of asthmatics, EPA believes it is consistent with Congressional intent to consult with FDA in making decisions regarding the amount of CFCs necessary for the production of MDIs.

Another commenter stated that EPA, in deferring to FDA's decision regarding the volume of essential use allowances, renders meaningless the requirement that EPA, not FDA, give interested parties notice and opportunity to comment on the allocation process. This commenter believed that MDI manufacturers must have meaningful participation in the allocation process, and that EPA has delegated this critical decision to FDA, precluding such participation.

EPA disagrees with this characterization of the process leading to the allocation. In fact, EPA extensively reviewed the public comments on the interim final rule with FDA. This allowed a joint reassessment of the determination of the amount of CFCs necessary. The initial determination on the amount of CFCs necessary was revised based on additional information submitted by stakeholders in response to the interim final rule. In the future, this same type of consultation between the agencies will occur on any comments that require a reassessment of the amount of CFCs necessary for use in medical devices. With this model, it is clear that MDI manufacturers do in fact have an avenue for actively participating in the allocation of CFCs for medical devices.

One commenter quoted a passage from the legislative history of the 1990 Amendments (S. Rep No. 228, 101st Cong., 1st Sess. 1989, 1990). The commenter stated that this passage says nothing about FDA being required to determine the quantity of ODS that is essential. In response, we note that the passage simply does not provide any information regarding interpretation of the phrase: ''if such authorization is determined by the Commissioner, in consultation with the Administrator, to be necessary for use in medical devices.'' In fact, the original Senate language regarding the exception for medical devices was somewhat different from what appears in the 1990 Amendments. Thus, this passage from the legislative history is of limited use.

One commenter stated that EPA and FDA's interpretation of the definition of medical device at section 601(8)(B) could undermine the clear intent of Congress in enacting Title VI to phase-out CFC-containing products. According to the commenter, allowing new ODS products with existing active moieties to be automatically deemed essential can only perpetuate the use of CFC MDIs. The commenter goes on to assert that this would likely encourage some U.S. companies to continue to formulate new CFC MDIs at the same time that other companies are diligently working to transition away from CFC products. Finally, this commenter states that the EPA and FDA interpretation is inconsistent with the overarching objective of the Montreal Protocol, which is the phase-out of ODS.

FDA's proposed rule on determinations of essentiality will govern the transition to CFC-free alternatives in a manner that protects both the environment and the health of patients who require these medications. EPA is managing this transition in accordance with the provisions set forth by the CAA and Decisions of the Parties to the Montreal Protocol, and does not believe that its interpretation of the CAA as explained in this preamble will in any way delay the transition to CFC-free alternatives. EPA is allocating essential use allowances according to FDA's definition of essentiality to ensure that patients continue to have access to life saving asthma and respiratory disease medication. The potential entry of a new CFC-MDI product that contains an active moiety that is already considered essential under both the Montreal Protocol and FDA's proposed transition rule would not have any additional environmental impact since the number of asthmatics requiring medication does not increase to reflect growth in of the number of different products containing the same active moiety.

One commenter stated that there is no basis in the CAA for changing the longstanding system for determining the essential use allowance allocations, and that there is no language in the CAA that suggests an intention to modify the essential use allocation system in any respect in the year 2000.

This statement is incorrect. As explained in the NPRM, and the IFR, prior to the year 2000, EPA allocated essential use exemptions under the original phase-out schedule contained in section 604(a) of the Act. This schedule does not require the complete phase-out of any ODS prior to calendar year 2000. Under section 606 of the Act, EPA was obligated to create an accelerated phase-out through regulation to match the accelerated phase-out under the Protocol. However, EPA had the flexibility to create exemptions to the regulatory phase-out, 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 phase-out date under Section 604 of the Act for all class I substances with the exception of methyl chloroform and methyl bromide. Because the phase-out date for CFCs has passed, EPA is no longer be able to authorize production of that substance on the basis of the slower phase-out schedule under the Act. Therefore, in this rulemaking, EPA has implemented for the first time the essential use exemption for medical devices in section 604(d)(2).

We note that EPA clearly stated in establishing the pre-2000 framework for essential uses that it was not at that time implementing the exemptions in section 604(d) of the statute, but was instead simply ensuring that exemptions approved under the Protocol were consistent with the phase-out schedule

in section 604(a). Thus, in its 1994 proposed rule, EPA stated: ''Section 604 of the CAA authorizes the granting of specific exemptions from the phase-out schedules contained in the Clean Air Act * * * [including] for limited quantities of class I substances solely for use in medical devices if such authorization is determined to be necessary * * * In today's action, EPA does not propose essential uses under the provisions of the CAA. However, EPA does propose to permit continued production for the essential uses authorized under the Protocol, so long as these essential use exemptions do not exceed amounts allowed in the schedule contained in section 604(a) of the CAA.'' 59 FR 56283 (November 10, 1994). Thus, it is clear that in establishing the pre-2000 essential use framework, EPA was working within the language of section 604(a), and not section 604(d). As a result, the commenter's statement that EPA is changing its ''long standing interpretation'' of section 604(d)(2) is incorrect.

One commenter stated that there is nothing in the legislative history that suggests any intention to modify the system [of essential use allowances] that has been followed for over a decade. In this regard, the statutory text is clear on its face. As explained above, in this rulemaking EPA is interpreting CAA section 604(d)(2) for the first time. In the 1990 Amendments, Congress established the year 2000 as the phase-out date for most class I ODS. This is reflected both in the table in 604(a) and in 604(b), which states: ''Effective January 1, 2000 * * * it shall be unlawful for any person to produce any amount of a class I substance.'' Section 604(d)(2) states that ''notwithstanding the termination of production required by subsection (b),'' EPA shall, if certain requirements are met, ''authorize the production of limited quantities of class I substances solely for use in medical devices.'' Thus, Congress clearly gave the year 2000 special significance, and just as clearly indicated that section 604(d)(2) governs the essential use process with respect to medical devices after January 1, 2000. As a result, EPA does not have the option of continuing with the pre-2000 essential use process, but rather must implement section 604(d)(2).

This commenter also stated that FDA and EPA had acted in contravention of the Waxman-Hatch Act by reducing the amount of essential use allowances available to a generic MDI manufacturer. The commenter went on to point out that the prevalence of asthma is increasing in this country, in particular among low income and minority populations. They state that EPA and FDA's actions reducing the allocation of CFCs for a company that produces low-cost generic MDIs threatens the public health and represents an unreasonable agency action.

EPA disagrees strongly with this characterization. EPA in allocating CFCs for use in metered dose inhalers, and FDA in setting up the framework for the transition to CFC-free asthma medications, are committed to managing the transition in a manner that in no way compromises the public health of any population while carrying out a Congressional directive. Congress clearly did not intend for EPA to authorize unlimited amounts of CFCs for use in MDIs. Instead, section 604(d)(2) requires that EPA only allocate the amount of CFCs that are ''necessary'' as determined by FDA in consultation with EPA. Both agencies are committed to providing enough essential use allowances to protect the public health while fulfilling our obligations under the CAA and the Montreal Protocol. Additionally, in the case of this particular company, the allocation they received in the IFR was higher than the largest amount of CFCs they have used to produce MDIs in any year since 1996. While, EPA and FDA understand the need for this and all companies to have some flexibility on the amount of CFCs available to them, in this particular case, both Agencies believe that a sufficient amount of flexibility was already built into the allocation in the IFR. Thus, EPA and FDA believe that the availability of low cost generic drugs to poor populations will not be affected by allocating CFCs to this company in the amount published in the IFR.

This commenter also stated that the impact on the ozone layer from CFC-MDIs is negligible. Under the terms of the Montreal Protocol and as mandated by the CAA, EPA implements the phase-out of the production and import of CFCs for all uses. At the same time, Congress and the Parties to the Protocol understood the need to continue to provide CFCs to produce CFC-MDIs until safe and effective alternatives are available. As evidenced by today's rule and the essential use allocation process since 1996, EPA and FDA are also committed to providing CFCs for necessary for use in MDIs until a product is no longer considered essential.

One commenter stated that FDA and EPA now have discretionary authority under the CAA to require *de novo* review of the essentiality of all CFC-containing products. Section 604 of the CAA provides for the phase out of all class I substances by January 1, 2000. The use of CFCs in MDIs is exempted from this requirement by section 604(d)(2) which authorized the use of CFCs in MDIs but only to the extent ''consistent with the Montreal Protocol.'' Under the Montreal Protocol, Decision IV/25 states that the use of CFCs in an MDI product is essential only if the product is ''necessary for the health * * * of society''. This commenter also states that it is evident that new CFC MDI products containing the same active moieties already available in existing products do not automatically meet this criteria.

The commenter may be confusing the domestic and international processes for determining essentiality. The criteria for determining essentiality that appear in Decision IV/25 are used only in the international process. The Parties apply the criteria in Decision IV/25 in deciding whether a specified quantity of CFCs is essential during a specified year for a specified use. In managing the domestic process, EPA and FDA look to the requirements of Title VI of the CAA, in particular the language of sections 601(8) and 604(d)(2). One of the requirements of section 604(d)(2) is that allocations are to be ''consistent with the Montreal Protocol.'' EPA considers allocations to be ''consistent with the Montreal Protocol'' if the Parties have approved the allocated quantities (or greater quantities) for the specified uses during the specified time period. Hence, EPA will interpret this comment as a set of recommendations for the application of the criteria in Decision IV/25 to future nominations.

One commenter stated that while they were pleased to see that EPA had not allocated as much as proposed, that EPA still was not in compliance with Section 604 of the CAA. This commenter stated that pursuant to their comments submitted on the NPRM, EPA should not authorize essential use allowances for the production of CFC-based albuterol MDIs since there is a CFC-free alternative on the market. EPA believes that we addressed this comment fully in the preamble to the Interim Final Rule (65 FR 716).

One commenter stated that she is an asthma and allergy sufferer and that she currently uses a variety of medications to treat these conditions, including MDIs containing CFCs. However, the commenter stated that she would appreciate help in getting better medications that contain no CFC's since she is also an environmentalist and also concerned about the environment.

EPA is committed to balancing the dual goals of protecting patient health and the environment by nominating essential uses to the Parties to the

Montreal Protocol and allocating essential use allowances in a manner consistent with both the Protocol and the CAA. We understand that it is critical that these essential use allowances continue to be provided to companies who produce medical devices essential for the health and well-being of asthmatics in this country. However, EPA continues to work hard in areas such as outreach and education to facilitate the transition to CFC-free products for the treatment of asthma and chronic obstructive pulmonary disease. EPA refers the commenter to the following sources of information which provide information on the current status of the transition to CFC-free alternatives:

1. The EPA stratospheric protection website at *http://www.epa.gov/ozone/mdi/mdi.html*

2. The FDA website at *http://www.fda.gov/cder/mdi/*

3. The National Asthma Education and Prevention Program website at *http://www.nhlbi.nih.gov/health/public/lung/asthma/mdiintro.htm.*

V. Administrative Requirements

A. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), P.L. 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 phase-out 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 this 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, EOA did not consider the use of any voluntary consensus standards.

H. Executive Order 13132 (Federalism)

Executive Order 13132, entitled ''Federalism'' (64 FR 432255, 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 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 theat 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 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 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 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 to 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 the 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 the action in the **Federal Register**. Under Section 307(b)(2), the requirements of this rule may not be challenged later in the 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. As

stated previously, EPA has made such a good cause finding, including the reasons therefor, and established an effective date of June 30, 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, Imports, Ozone layer, Reporting and recordkeeping requirements.

Dated: June 22, 2000.

Carol M. Browner,

Administrator.

40 CFR Part 82 is to be 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 is amended by revising the table in paragraph (t)(2) to read as follows:

§ 82.4 Prohibitions.

* * * * *

(t) * * *

(2) * * *

TABLE 1—ESSENTIAL USE ALLOCATION FOR CALENDAR YEAR 2000

Company	Chemical	Quantity (metric tons)
(i) Metered Dose Inhalers (for oral inhalation) 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, Aventis (formerly Rhone-Poulene Rorer), 3M.	CFC–11 or CFC–12 or CFC–114	2038.0
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
(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

[FR Doc. 00–16628 Filed 6–29–00; 8:45 am]
BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Office of Inspector General

42 CFR Parts 409, 410, 411, 412, 413, 419, 424, 489, 498, and 1003

[HCFA–1005-N5]

RIN 0938–AI56

Medicare Program; Prospective Payment System for Hospital Outpatient Services; Delay of Effective Date

AGENCY: Health Care Financing Administration (HCFA), HHS, and Office of Inspector General (OIG), HHS.

ACTION: Notice of delay of effective date for final rule with comment period.

SUMMARY: This document delays the effective date on a final rule with comment period published in the **Federal Register** on April 7, 2000 (65 FR 18434). That rule implemented a prospective payment system for hospital outpatient services furnished to Medicare beneficiaries, as set forth in section 1833(t) of the Social Security Act. It also established requirements for provider departments and provider-based entities, and it implemented section 9343(c) of the Omnibus Budget Reconciliation Act of 1986, which prohibits Medicare payment for nonphysician services furnished to a hospital outpatient by a provider or supplier other than a hospital, unless the services are furnished under an arrangement with the hospital. In addition, the rule established in regulations the extension of reductions in payment for costs of hospital outpatient services required by section 4522 of the Balanced Budget Act of 1997, as amended by section 201(k) of the Balanced Budget Refinement Act of 1999. The effective date is delayed from July 1, 2000 to August 1, 2000.

DATES: *Effective date:* August 1, 2000, except that the changes to § 412.24(d)(6), new § 413.65, and the changes to § 489.24(h), § 498.2, and § 498.3 are effective October 10, 2000.

Applicability date: For Medicare services furnished by hospitals that are subject to the prospective payment system, including hospitals excluded from the inpatient prospective payment system, and by community mental health centers, the applicability date for implementation of the hospital outpatient prospective payment system is August 1, 2000.

FOR FURTHER INFORMATION CONTACT: Janet Wellham, (410) 786–4510.

SUPPLEMENTARY INFORMATION:

I. Background

On April 7, 2000, we issued a final rule with comment period in the **Federal Register** (65 FR 18434) that reflected the provisions of the September 8, 1998 proposed rule (63 FR