which case no collocation requirement applies. State and local air monitoring agencies must use methodologies and quality assurance/quality control (QA/QC) procedures approved by the EPA Regional Administrator for these required continuous analyzers.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[EPA–HQ–OAR–2006–0159; FRL–8325–5]

RIN 2060–AN81

Protection of Stratospheric Ozone: Allocation of Essential Use Allowances for Calendar Year 2007

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: With this action, EPA is allocating essential use allowances for import and production of Class I stratospheric ozone-depleting substances (ODSs) for calendar year 2007. Essential use allowances enable a person to obtain controlled Class I ODSs as part of an exemption to the regulatory ban on the production and import of these chemicals, which became effective as of January 1, 1996. EPA allocates essential use allowances for exempted production or import of a specific quantity of Class I ODSs solely for the designated essential purpose. The allocations in this action total 167.0 metric tons (MT) of chlorofluorocarbons (CFCs) for use in metered dose inhalers (MDIs) for 2007.

DATES: Effective Date: This final rule is effective June 12, 2007.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2006–0159. All documents in the docket are listed on the *www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. This Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Air Docket is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Kirsten Cappel, by regular mail: U.S. Environmental Protection Agency, Stratospheric Protection Division (6205J), 1200 Pennsylvania Ave., NW., Washington, DC 20460; by courier service or overnight express: 1310 L Street, NW., Room 1047C, Washington, DC 20005; by telephone: (202) 343–9556; by fax: (202) 343–2338; or by, e-mail: *cappel.kirsten@epa.gov*.

SUPPLEMENTARY INFORMATION:

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I. Basis for Allocating Essential Use Allowances

A. What are essential use allowances?

Essential use allowances are allowances to produce or import certain ODSs in the U.S. for purposes that have been deemed ''essential'' by the U.S. Government and by the Parties to the Montreal Protocol on Substances that Deplete the Ozone Layer (Montreal Protocol).

The Montreal Protocol is an international agreement aimed at reducing and eliminating the production and consumption[1] of ODSs. The elimination of production and consumption of Class I ODSs is accomplished through adherence to phase-out schedules for specific Class I ODSs,[2] which include CFCs, halons, carbon tetrachloride, and methyl chloroform. As of January 1, 1996, production and import of most Class I ODSs were phased out in developed countries, including the United States.

However, the Montreal Protocol and the Clean Air Act (the Act) provide exemptions that allow for the continued import and/or production of Class I ODSs for specific uses. Under the Montreal Protocol, exemptions may be granted for uses that are determined by the Parties to be ''essential.'' Decision IV/25, taken by the Parties to the Protocol 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 criteria for an essential use, as set forth in paragraph 1 of Decision IV/25, are the following:

''(a) 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;

(b) 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.''

[1] ''Consumption'' is defined as the amount of a substance produced in the United States, plus the amount imported into the United States, minus the amount exported to Parties to the Montreal Protocol (see Section 601(6) of the Clean Air Act).

[2] Class I ozone depleting substances are listed at 40 CFR Part 82 subpart A, appendix A.

B. Under what authority does EPA allocate essential use allowances?

Title VI of the Act implements the Montreal Protocol for the United States. Section 604(d) of the Act authorizes EPA to allow the production of limited quantities of Class I ODSs after the phaseout date for the following essential uses:

(1) Methyl chloroform, ''solely for use in essential applications (such as nondestructive testing for metal fatigue and corrosion of existing airplane engines and airplane parts susceptible to metal fatigue) for which no safe and effective substitute is available.'' Under the Act, this exemption was available only until January 1, 2005. Prior to that date, EPA issued methyl chloroform allowances to the U.S. Space Shuttle and Titan Rocket programs.

(2) Medical devices (as defined in section 601(8) of the Act), ''if such authorization is determined by the Commissioner [of the Food and Drug Administration], in consultation with the Administrator [of EPA] to be necessary for use in medical devices.'' EPA issues allowances to manufacturers of MDIs, which use CFCs as propellant for the treatment of asthma and chronic obstructive pulmonary disease.

(3) Aviation safety, for which limited quantities of halon-1211, halon-1301, and halon-2402 may be produced ''if the Administrator of the Federal Aviation Administration, in consultation with the Administrator [of EPA] determines that no safe and effective substitute has been developed and that such authorization is necessary for aviation safety purposes.'' Neither EPA nor the Parties have ever granted a request for essential use allowances for halon, because in most cases alternatives are available and because existing quantities of this substance are large enough to provide for any needs for which alternatives have not yet been developed.

The Parties to the Montreal Protocol, under Decision XV/8, have additionally allowed a general exemption for laboratory and analytical uses through December 31, 2007. This exemption is reflected in EPA's regulations at 40 CFR part 82, subpart A. While the Act does not specifically provide for this exemption, EPA has determined that an allowance for essential laboratory and analytical uses is allowable under the Act as a *de minimis* exemption. The *de minimis* exemption is addressed in EPA's final rule of March 13, 2001 (66 FR 14760–14770). The Parties to the Protocol subsequently agreed (Decision XI/15) that the general exemption does not apply to the following laboratory and analytical uses: Testing of oil and grease, and total petroleum hydrocarbons in water; testing of tar in road-paving materials; and forensic finger-printing. EPA incorporated this exclusion at Appendix G to subpart A of 40 CFR part 82 on February 11, 2002 (67 FR 6352).

C. What is the process for allocating essential use allowances?

Before EPA allocates essential use allowances, the Parties to the Montreal Protocol must first authorize the United States' request to produce or import essential Class I ODSs. The procedure set out by Decision IV/25 calls for individual Parties to nominate essential uses and the total amount of ODSs needed for those essential uses on an annual basis. The Montreal Protocol's Technology and Economic Assessment Panel (TEAP) evaluates the nominated essential uses and makes recommendations to the Parties. The Parties make the final decisions on whether to authorize a Party's essential use nomination at their annual meeting. This nomination cycle occurs approximately two years before the year in which the allowances would be in effect. The allowances allocated through today's action were first nominated by the United States in January 2005.

Once the Parties authorize the U.S. nomination, EPA allocates essential use exemptions to specific entities through notice-and-comment rulemaking in a manner consistent with the Act. For MDIs, EPA requests information from manufacturers about the number and type of MDIs they plan to produce, as well as the amount of CFCs necessary for production. EPA then forwards the information to the Food and Drug Administration (FDA), which determines the amount of CFCs necessary for MDIs in the coming calendar year. Based on FDA's determination, EPA proposes allocations for each eligible entity. Under the Act and the Montreal Protocol, EPA may allocate essential use allowances in quantities that together are below or equal to the total amount authorized by the Parties. EPA will not allocate essential use allowances in amounts higher than the total authorized by the Parties. For 2007, the Parties authorized the United States to allocate up to 1,000 MT of CFCs for essential uses. In a notice of proposed rulemaking published in the **Federal Register** on November 3, 2006 (71 FR 64668), EPA proposed to allocate 125.3 MT.

D. What quantity of essential use allowances is EPA allocating?

EPA proposed to allocate 125.3 MT of essential use allowances for 2007 in its November 2006 proposed rule. With today's final action, EPA is allocating 167.0 MT of essential use allowances for 2007 for the production and import of CFCs for the manufacture of essential use MDIs. EPA is allocating this amount based on a revised determination letter by FDA dated May 4, 2007. EPA has placed this revised determination letter in the docket for review. This quantity of 167.0 MT includes two increases from the amounts proposed in November 2006. First, EPA is allocating 22.4 MT to Armstrong Pharmaceuticals, Inc. (an increase from a proposed allocation of 0.0 MT) for the manufacture of epinephrine; second, EPA is allocating an additional 19.3 MT to 3M Pharmaceuticals (65.0 MT total for 2007) for the manufacture of essential use MDI products (Aerobid, Aerobid M, and Maxair Autohaler). The total allocation for 2007 of 167.0 MT is far below the 1,000 MT that the Parties to the Montreal Protocol authorized for the United States for 2007. It is also a significant reduction from the 1,002.4 MT allocated for 2006. These reductions demonstrate the U.S. commitment to decreasing the amount of CFCs allocated for essential uses. Furthermore, the 167.0 MT does not include an allocation for the manufacture of CFC-albuterol MDIs, indicating that the transition to non-CFC alternatives for this application is well underway.

In its revised determination letter FDA informed EPA that Armstrong needed 22.4 MT of CFCs to manufacture generic epinephrine in 2007. EPA and FDA are allocating this amount to Armstrong to acquire CFC–114 for the manufacture of epinephrine, not CFCs to manufacture CFC-albuterol. In the revised determination letter, FDA articulated that Armstrong's allocation is specific to CFC–114 for the production of epinephrine MDIs. FDA stated, ''In recent years, we aggregated the amounts for CFC–11, –12, –114 and provided recommendations on the total amounts of CFC necessary to protect the public health. This year, we provide recommendations for aggregated amount of CFCs, with one exception. We recommend that Armstrong Pharmaceuticals receive an allocation of 22.4 tonnes of CFC–114 for the manufacture of epinephrine CFC MDIs. We believe that this specific allocation is necessary to protect the public health, given the current essentiality determination as contained in 21 CFR 2.125(e).'' Consistent with FDA's

determination letter, EPA is allocating 22.4 MT of CFC–114 to Armstrong for the production of epinephrine MDIs for 2007.

FDA also informed EPA in its revised determination letter that it determined that 3M needed an additional 19.3 MT of essential use allowances to manufacture essential use MDI products. These products include Aerobid, Aerobid M, and Maxair Autohaler.

FDA noted to EPA that in making its revised determination, FDA reviewed supplementary information from MDI manufacturers, including more recent data on the quantities and types of CFCs held as well as more specific information on manufacturers' production plans for 2007. Based on this information, FDA recalculated the quantities and types of CFCs that would be medically necessary and recommended small increases in the allocations for two MDI manufacturers for calendar year 2007. In addition, FDA informed EPA that it applied the terms of Decision XVII/5, including the provision that each manufacturer maintain no more than a one-year operational supply of CFCs for essential uses.

II. Response to Comments

EPA received comments from twelve entities on the proposed rule, as discussed below.

A. Proposed Level of Allocations

One commenter opposed as too low EPA's proposed allocation of 125.3 MT of CFCs for MDIs, given that the Parties to the Montreal Protocol authorized 1,000 MT. The commenter stated that 125.3 MT would not suffice to ensure the continuous availability of CFCs necessary to meet expected demand. The commenter noted that the facility being used to produce CFC–11 and CFC–12 is the only facility doing so and it is sized for far larger volumes of production. According to the commenter, continuing to decrease the size of production runs makes manufacturing more inefficient, complex, and costly. The commenter urged EPA to set policies that enable the manufacture of CFCs and allow producers and users the ability to shift unused allocations from one year to the next so that supply can be more easily assured. In addition, the commenter urged EPA to re-allocate essential use allowances in 2007 for essential use CFCs that were not produced and subsequently conferred in 2006. The commenter also noted that production of CFC–114 during 2006 was not adequate to meet MDI producer demand for which 2006 essential use allowances existed.

A second commenter provided similar comments and noted concern that qualified CFC producers may not be able or willing to produce a reliable supply in future years, citing the CFC–114 production shortfalls experienced by Honeywell as an example. The commenter expressed support for efforts by the U.S. Government to work with other Parties to the Montreal Protocol to establish a process for assessing the need for and feasibility of a final production campaign; the commenter stated that such efforts would support the ultimate phaseout of CFC production for MDIs while protecting public health by ensuring a smooth transition for MDIs.

A third commenter also opposed as too low the quantity of essential use allowances proposed for allocation. The commenter submitted two sets of comments, one of which was supplementary and received after the end of the comment period, but which EPA considered. Both sets of comments were submitted as confidential business information (CBI); EPA has placed redacted versions of them in the docket. The commenter indicated that it received a proposed allocation of zero metric tons and urged EPA to allocate additional allowances so that it could meet anticipated market demand for CFC-albuterol and CFC epinephrine in 2007 and 2008. The commenter noted that with the withdrawal of Schering-Plough from the CFC market, Armstrong would be only manufacturer of CFC-albuterol. In addition, the commenter asserted, the elimination of Schering-Plough's Warrick branded CFC-albuterol product will create a dramatic shortfall in the supply of CFC inhalers and is likely to lead to serious market disruption unless Armstrong increases production to meet demand. The commenter urged EPA to provide for its propellant needs for both 2007 and 2008 in the 2007 rule. To support its argument, the commenter provided data from IMS, a pharmaceutical market research firm, indicating market trends of CFC-albuterol that suggest in 2006, CFC-albuterol comprised a significant amount of the total albuterol market.

A fourth commenter that submitted CBI comments requested additional CFCs to manufacture its essential use MDIs. A redacted version of these comments has been placed in the docket. The commenter requested an additional 19.3 MT of CFCs to manufacture Aerobid, Aerobid M, and Maxair Autohaler. The commenter stated that without the additional allowances it would likely be unable to manufacture all of the MDIs forecasted by two of its customers.

Another commenter noted that it understood the zero allocation proposed for its company for 2007 and stated that it has been working to acquire existing CFCs to satisfy essential needs.

EPA also received comments that either supported the proposed allocations—in whole or in part—or believed they should be lower. One commenter stated that there should be no exemptions for any ODS. The commenter stated that allowing exemptions discourages the development of alternatives.

Seven commenters supported some or all of the proposed allocations for 2007. Four expressed approval of EPA's allocation of zero essential use allowances for manufacture of albuterol MDIs, as determined by FDA. One commenter additionally stated that by allocating only what was necessary and not the entire amount allowed by the Parties, FDA and EPA are supporting the over-arching goals of the Montreal Protocol. The commenter also noted that the proposed allocations are consistent with FDA's final determination on albuterol non-essentiality and that EPA's phaseout timeline fully agrees with FDA's conclusions that an effective and orderly transition to HFA MDIs would be complete by December 31, 2008.

One commenter supported EPA's choice to allocate only a portion of the essential use allowances granted to the United States by the Parties to the Montreal Protocol. The commenter stated that it supports EPA's decision to eliminate essential use allowances for those companies currently marketing both CFC and non-CFC albuterol MDIs. The commenter stated that the existing CFC stockpiles in the United States will be adequate to assure a smooth and timely transition to non-CFC albuterol inhalers.

EPA received two sets of CBI comments from one commenter, both of which were received after the close of the comment period, but which EPA considered, which supported EPA's proposed zero allocation for the manufacture of CFC-albuterol MDIs. EPA has placed redacted versions of the comments in the docket. The commenter supported the proposed allocations, specifically the proposed zero allocations for albuterol MDIs containing CFCs. The commenter argued that the proposed zero allocation will facilitate the orderly transition to HFA albuterol inhalers, minimize the confusion and related compliance and safety issues raised by patients alternating between CFC and HFA

inhalers, and ensure that additional CFCs are not needlessly released into the environment.

The commenter noted that it had already begun to transition its supply of CFC-based albuterol inhalers to HFA inhalers. Additionally, the commenter asserted that an early transition to HFA inhalers would allow manufacturers, physicians, and pharmacists to act in a coordinated manner to educate patients and transition them in an orderly fashion. It noted that there are important differences between CFC and HFA inhalers that require patient counseling and that without an early and orderly transition facilitated by patient education and training, many patients will switch back and forth between the two inhalers or wait until the last minute.

The commenter further noted that to support the transition to HFA-based albuterol, it has dedicated significant resources to support patients, physicians, pharmacists, and other stakeholders. The commenter stated that it had significantly increased the production of HFA albuterol inhalers and that it has the ability to increase production further if there is need. Additionally, the commenter stated that it has implemented a comprehensive plan to communicate information regarding the transition to key stakeholders. The commenter also noted that it has a patient assistance program for low-income patients and patients without health insurance.

EPA allocates essential use allowances annually in accordance with the Act and the Montreal Protocol. For the 2007 control period, EPA, in consultation with FDA, evaluated the medical demand for essential use MDIs and determined the amount of CFCs needed to meet that demand. The U.S. Government first nominated an amount for essential use allowances for 2007 in January 2005 (1,493 MT). The Parties authorized 1,000 MT for the U.S. at the 17th Meeting of the Parties in 2006. Since the U.S. Government submitted its nomination for 2007, EPA and FDA have received more current information on the amount of CFCs needed to manufacture essential use MDIs, amounts of stockpiled CFCs available to manufacturers, and the availability of non-CFC alternatives. Neither the 1,493 MT nominated nor the 1,000 MT authorized accurately reflects the amount of CFCs necessary to meet medical needs in 2007.

In making its determination for 2007 essential use allowances, FDA informed EPA that it undertook a similar analysis as completed in years past. FDA articulated to EPA that for each MDI manufacturer that requested essential use allowances, FDA evaluated a number of factors. FDA informed EPA that it took the following steps in making the 2007 determination for essential use allowances. First, FDA evaluated the medical necessity by evaluating the number of CFC MDIs necessary to protect public health in the U.S. (including consideration of current data on the prevalence of asthma and COPD) and the quantity of CFCs necessary to ensure the manufacture and continuous availability of those MDIs. Second, FDA analyzed the existing inventory of CFCs held by each MDI manufacturer as of May 1, 2006 and updated as of December 31, 2006. Third, FDA accounted for the implementation of the terms of Decision XVII/5, including the provision that manufacturers maintain no more than a one-year operational supply, and considered how manufacturers' existing CFC supplies would be drawn down as essential use MDIs were manufactured throughout the year. As was also articulated in the determination letter, revised May 4, 2007, FDA assumed that all manufacturers would procure the full quantity of CFCs allocated to them for the year.

In response to the comments recommending allocation of essential use CFCs for multiple years, although EPA recognizes the difficulties associated with producing small amounts of CFCs per year, the Parties authorized an essential use exemption for CFC production and import for the 2007 control period only. Therefore, in accordance with the Decisions of the Parties, the United States allocated allowances to MDI manufacturers for 2007 control period. EPA understands that the U.S. manufacturer can increase the efficiency of its production run by combining the amount allocated by EPA for essential use production of pharmaceutical-grade CFCs for domestic use with the amount permitted under the Montreal Protocol, and authorized by EPA, for production of pharmaceutical-grade CFCs for export to Article 5 and non-Article 5 Parties, recognizing that the manufacturer may incur the cost of destroying the non-pharmaceutical grade portion of the run. EPA understands that the design of the Montreal Protocol and Title VI of the Act anticipated that ODS costs would increase during the transition to alternatives. However, the United States Government expects that this issue of a need for campaign production to meet the essential use health needs for CFCs for MDIs globally will be raised by the Parties to the Montreal Protocol at future meetings.

With respect to the comments recommending higher allocations for 2007 to manufacture generic albuterol and generic epinephrine, FDA has informed EPA that additional essential use allowances will be needed for the manufacture of generic epinephrine in 2007. FDA made this determination based on information about the manufacturer's existing inventory, blend requirements, and production need, as well as implementation of the terms of Decision XVII/5, including the provision that manufacturers maintain no more than a one-year operational supply for CFCs for essential uses.

FDA informed EPA that it did not agree with the comment that additional amounts of CFCs need to be allocated for the manufacture of CFC-albuterol in 2007 to meet the overall demand for albuterol. In the September 2006 letter to EPA (revised in May 2007), FDA stated that its determination of the amount of CFCs necessary for production of essential use MDIs is lower than the total amount requested by manufacturers, and in reaching its estimate, FDA took into account the manufacturers' production of MDIs that used CFCs as a propellant in 2006, their estimated production in 2007, and stockpile levels (as of December 31, 2006). FDA also stated that it considered comments received on the proposed rule for the allocation of CFCs in 2007. Finally, as articulated in its letter, FDA took into account that, at the time of the letter, roughly 40 percent of the albuterol MDIs currently produced were propelled by HFAs (HFA–134a) rather than CFCs.

Given the publicly stated plans of Schering-Plough, a major albuterol CFC supplier, FDA has informed EPA that it believes the manufacture of CFC-albuterol will decrease in 2007 (and further decrease in 2008 as the phase-out date approaches). The manufacture and sale of albuterol HFA MDIs will increase sufficiently to meet the medical needs of patients for albuterol. FDA will continue to monitor closely the availability of albuterol to ensure that there is adequate supply to meet patient needs. FDA has informed EPA that HFA inhalers now make up approximately half the overall albuterol-levalbuterol inhaler market. Furthermore, according to FDA, HFA manufacturers report they currently have the ability to produce enough HFA albuterol MDIs to meet total market demand for albuterol MDIs.

With respect to the commenter that requested additional CFCs to manufacture its essential use MDIs (Aerobid, Aerobid M, and Maxair

Autohaler), FDA informed EPA that an increase of CFCs to 65.0 MT was necessary for 2007. FDA informed EPA that its revised determination was based on additional analysis of medical need and on supplementary information received from the MDI manufacturers, including more recent data on quantities of CFCs held. In addition, FDA informed EPA that it applied the terms of Decision XVII/5, including the provision that each manufacturer maintain no more than a one-year operational supply of CFCs for essential uses.

In response to the comment that there should be no exemptions for any ODS and that allowing exemptions discourages the development of alternatives, in this instance, EPA and FDA do not believe that the allocation of essential uses for the manufacture of CFC MDIs precludes the development of alternatives, in part because EPA and FDA consider a company's progress in research and development of alternatives in evaluating a company's request for an essential use exemption.

Finally, two commenters raised specific medical-related issues. One commenter, an asthmatic, expressed concern that the discontinuation of inhalers containing albuterol will leave no alternatives for asthmatics who are allergic to sulfites and sulfates. The commenter notes that he or she is allergic to sulfites and that the generic albuterol inhaler is going to be discontinued.

In response, FDA informed EPA that HFA albuterol MDIs do not contain sulfites. Indeed, unlike CFC albuterol products, each albuterol HFA has a unique formulation, which should allow patients to find a product they tolerate and find effective, even if they feel one particular product is not sufficiently tolerable.

A second commenter argued that the elimination of fluorocarbons is not necessary in aerosol albuterol items. The commenter stated that the non-aerosol form of albuterol poses several problems, such as difficulty in ascertaining when a canister is empty. In addition, the commenter noted that there is no sensation that a dosage of the non-aerosol medication is being received and that this may have profoundly negative medical repercussions. The commenter also asserted that because the disbursement of albuterol aerosol liquid goes into a mouth that is surrounding the canister and seals off the disbursement, no aerosol escapes into the surrounding atmosphere. Lastly, the commenter stated that the elimination of aerosol-dispensed respiratory medications will have a negative effect on patients.

In its March 31, 2005 final rule (70 FR 17168), FDA determined that albuterol will no longer be designated as an ''essential use'' after December 31, 2008. FDA discussed issues associated with the essentiality of albuterol in that rule. Today's final action allocating CFCs for the manufacture of MDIs does not address the essentiality of albuterol. EPA notes that the non-ODS albuterol MDIs (i.e. HFA-albuterol) that are currently available to patients also contain an aerosol, HFA–134a.

B. Consideration of Stocks of CFCs in the Allocation of Essential Use Allowances

One commenter stated that EPA should not allocate any new essential use allowances for 2007, claiming that existing stockpiles of CFCs must be used before new essential use allowances may be granted. The commenter stated that EPA's proposed essential use allowances for 2007 were in contravention of Decision IV/25 of the Montreal Protocol, which provides that production and consumption of CFCs for essential uses is permitted only if the CFCs are ''not available in sufficient quantity and quality from existing stocks.'' The commenter stated that where stockpiles are in excess of essential need, EPA should first seek voluntary transfers, and second redistribute CFC stockpiles to where they are most needed.

The commenter provided three supporting claims. First, the commenter provided data indicating that there are sufficient aggregate stockpiles available in the U.S. to cover the essential needs for 2007. The commenter recognized that these stockpiles are not evenly held by U.S. companies and urged EPA to take steps to redistribute them. Second, the commenter asserted that the Montreal Protocol and the Act support the ''reallocation'' of existing CFC stockpiles before new essential use allowances are allocated. The commenter argued that the objective of the Montreal Protocol supports an interpretation of Decision IV/25 that the Montreal Protocol Parties should deplete the aggregate CFC stockpiles available in their respective markets before allocating new essential use allowances to any MDI manufacturers. The commenter stated that it recognizes that Decisions XVII/5 and XVIII/7 state that Parties must consider the operational supply of each manufacturer in making essential use allowance decisions. However, the commenter asserted that it does not believe that these Decisions conflict with or supersede Decision IV/25 as the Parties can take into account both the aggregate CFC stockpile and each manufacturer's operational supply. Additionally, the commenter argued that Decision XII/2 provides for the transfer of essential use allowances and CFCs held by MDI producing companies in order to avoid unnecessary production. According to the commenter, Decision VII/28 provides for Parties, under certain circumstances, to reallocate excess essential use allowances or CFCs in their respective markets. Thus the commenter asserted that the Montreal Protocol supports compelling U.S. companies with excess CFCs to sell their stockpiles to the U.S. Government for reallocation.

Furthermore, the commenter argued that the Act, specifically Section 615, grants EPA the right to take certain actions to prevent endangerment to public health or welfare. The commenter asserted that unnecessary emissions of CFCs will endanger public health or welfare due to the effects of stratospheric ozone depletion, and that EPA is justified in promulgating regulations that would allow it to mandate the reallocation of excess stockpiled CFCs.

Lastly, the commenter stated that transfers or reallocations of CFCs are subject to all other Montreal Protocol (specifically, Decisions IV/25, XII/2, and XVII/5) and CAA parameters. Further, the commenter stated that EPA may not approve any transfer or reallocation of CFCs for any CFC MDI product approved after December 31, 2000 unless the essentiality criteria set out in paragraph 1(a) of Decision IV/25 are met, or to the extent the intended recipient maintains CFC stockpiles in excess of the one-year operational supply threshold.

In assessing the amount of new CFC production required to satisfy 2007 essential uses, just as in 2006, EPA and FDA applied the terms of Decision XVII/5 including the provision on stocks of CFCs that indicates Parties should allocate such that manufacturers of MDIs maintain no more than a one-year operational supply of CFCs for essential uses. FDA's approach for 2007 was similar to that for 2006; first it calculated the quantity that each MDI manufacturer needed to produce essential use MDIs for the year and then it subtracted from that quantity any CFC stocks owned by that MDI manufacturer exceeding a one-year operational supply. The remainder, if more than zero, is the quantity of newly produced or imported CFCs needed by that manufacturer. In addition, FDA has informed EPA that consistent with

Decision XVII/5, FDA evaluates each company on an individual basis, rather than an aggregate of all MDI manufacturers. So, while amounts of CFCs may be available for purchase in the marketplace, FDA and EPA only account for stocks owned by a particular MDI manufacturer in evaluating that manufacturer's CFC need.

EPA agrees with the commenter that the objective of the Montreal Protocol is to reduce and eventually eliminate the production of ODSs, but that the essential use provision exists to ensure that an adequate supply of CFCs are available for those uses deemed ''essential'' by the Parties. EPA recognizes that in making the determination for essential uses for 2007, FDA took into account a number of considerations in assessing each MDI manufacturer's need, including the amount and type of CFC necessary to produce specific MDIs. The commenter's recommendation about redistribution of excess CFCs is outside the scope of the proposal on which this final rule is based. While the commenter suggests that EPA use Section 615 authority to redistribute excess CFCs, EPA does not believe that government-mandated redistribution is necessary at this time, and has not examined the extent of its authority for such action. EPA regulations currently allow transfer of both essential use allowances and essential use CFCs among essential use allowance holders. These mechanisms provide for redistribution of CFCs with minimal government involvement. The small number of participants in the market for essential use CFCs and the limited quantities of CFCs at issue further suggest that there is no need to expand EPA's role. In addition, any entity that chooses to hold stocks of essential use CFCs rather than sell to a willing purchaser runs the risk that the stocks will decline in value and ultimately become a liability for domestic use.

EPA regulates transfers of essential use CFCs to ensure their proper use, and in approving transfers between domestic MDI manufacturers, EPA requires the companies involved to certify that the MDIs produced with the transferred essential use CFCs were approved by FDA before December 31, 2000. EPA does not apply the terms of Decision XVII/5, including the provision on manufacturers maintaining no more than a one-year operational supply, when assessing whether to approve a transfer of essential use CFCs. However, in determining annual essential use allocations for MDI manufacturers, FDA analyzes each MDI manufacturer's stocks of CFCs. Therefore, if a company obtains essential use CFCs during a particular year from another MDI manufacturer, FDA would account for those stocks in making its determinations for the year. EPA encourages, but does not mandate, such transfers.

A second commenter noted that based on the projected use of its 2006 stockpile amounts, it would require additional CFCs to meet the increased demand for albuterol MDIs and epinephrine mist MDIs. EPA and FDA disagree with the commenter that additional essential use allowances should be allocated in 2007 for the production of CFC-albuterol MDIs. EPA and FDA believe that the commenter's projections assume a level of production exceeding that medically necessary. Further, this comment does not take into account all CFCs available to the company for albuterol production. When these factors are considered, EPA believes, based on consultation with FDA, that no additional CFC allowances for albuterol should be allocated in 2007.

C. Number of Months of Safety Stockpile

One commenter supported the zero allocation for albuterol manufacture in 2007, but voiced concern with the method by which FDA calculated essential use allowances. The commenter noted that while FDA appeared to have based its allocation recommendation on the operational supply rule established by paragraph 2 of Decision XVII/5, FDA implemented this paragraph by setting the minimum stockpile threshold at 12 months (as articulated in EPA's final rule allocating 2006 essential use allowances) while the Decision states that 12 months is the maximum operational supply that may be maintained by an MDI manufacturer. Recognizing that the Decision allows Parties to set the operational supply threshold at less than one year, the commenter recommended a threshold of one to three months.

A second commenter noted that FDA applied the twelve-month cap on each company's operational supply of CFCs, as stated in paragraph 2 of Decision XVII/5, to determine that no allocations for manufacturers of CFC albuterol MDIs were necessary. The commenter stated that this interpretation was ''logical, reasonable, and equitable,'' but further stated that the twelve-month stockpile supply is a maximum amount and that a six-month supply stockpile allowance should be used in any future assessments of allocations.

A third commenter expressed support for the calculation of anticipated CFC requirements for future manufacture of albuterol MDIs, as described in the proposed rule, and stated that the calculation is both reasonable and appropriate to ensure a smooth transition. The commenter noted that sufficient stockpiles of CFCs exist to meet albuterol CFC MDI production needs through the end of 2008. In addition, the commenter stated that an orderly transition to albuterol HFA implies a phase-out of albuterol CFC production before the December 31, 2008 deadline. After that deadline, section 610 of the Clean Air Act will prohibit the sale or distribution of albuterol CFC MDIs in interstate commerce. Therefore, the commenter states, retailers and suppliers must have adequate time to deplete their stock before then.

Paragraph 2 of Decision XVII/5 states that Parties ''shall take into account pre- and post-1996 stocks of controlled substances as described in paragraph 1(b) of Decision IV/25, such that no more than a one-year's operational supply is maintained by that manufacturer.'' In making its determination for allocation of essential use allowances, FDA acted consistent with this provision by allowing manufacturers to maintain a supply of up to 12 months of the manufacturing operations. FDA calculates volumes to allow the manufacturer to end the calendar year with the appropriate level of stock. EPA and FDA do not agree that allowing manufacturers to maintain up to a 12-month supply is excessive because, in part, maintaining such an amount accounts for unexpected variability in the demand for MDI products or other unexpected occurrences in the market and therefore ensures that MDI manufacturers are able to produce their essential use MDIs.

D. Rulemaking Process and Timing

One commenter requested that EPA reconsider its allocations in light of Schering-Plough's October 13, 2006 announcement that it would end production of its Warrick Pharmaceutical brand CFC-albuterol MDIs early in 2007. According to the commenter, most customers believe that Warrick brand CFC-albuterol will not be available after early 2007. In this regard, the commenter noted that after the first quarter of 2007, Armstrong will be the sole producer and supplier of albuterol CFCs and that EPA must make an additional CFC allocation to Armstrong in order to avoid a dramatic shortfall in CFC supply relative to projected demand.

With Schering-Plough's announcement, EPA and FDA expected

that the manufacture of CFC-albuterol would be significantly lower in 2007 than 2006 and that this decrease will be balanced by an increase in HFA production and availability sufficient to meet patient needs. EPA and FDA expect a further decrease in albuterol CFC production in 2008, particularly in the months leading up to December 31, 2008, when all sales of CFC albuterol MDIs must cease. FDA has informed EPA that based on information it is receiving from HFA manufacturers, HFA manufacturers currently have the ability to produce enough HFA albuterol MDIs to meet total market demand for albuterol MDIs. Therefore FDA does not anticipate shortages of albuterol MDIs.

One commenter indicated that it believed that CFCs should not be allocated to companies unless they have demonstrated good faith efforts to research and develop CFC-free alternatives. The commenter argued that EPA's interpretation of Paragraph 1 of Decision VIII/10—that the Parties will request information on research and development from companies but not use it as a basis for denying an essential use allowance request—is inadequate. The commenter asserted that the reiteration of the same language from Paragraph 1 of Decision XVIII/10 in Paragraph 3 of Decision XVIII/7 indicates that Parties did not believe that the plain intent of Decision VIII/10 was being followed and that at this stage of the phaseout the Parties are looking for demonstrations of commitment to the transition. The commenter also argued that Decisions VIII/10 and XVIII/7 warrant EPA to require companies requesting essential use allowances to demonstrate ongoing research and development of CFC-free alternatives and that EPA has the authority to do so under Sections 604(d)(2) and 615 of the CAA.

EPA agrees that companies applying for essential use allocations to manufacture MDIs generally should demonstrate ongoing research and development of alternatives to CFC MDIs. To this end, in accordance with Decision VIII/10, since 1997 EPA has requested that applicants provide this information with their applications for CFC essential use nominations. EPA reiterated this policy in the final rules allocating essential use allowances for 2005 and 2006 (70 FR 49836 and 71 FR 58504, respectively). Each company that is receiving an essential use allocation has submitted information to EPA pertaining to its research and development efforts. In its essential use nominations, the U.S. Government articulates that the MDI manufacturers, for which the U.S. Government is submitting an essential use request, have submitted information demonstrating their on-going research and development activities in pursuit of alternatives to CFC MDIs. To this end, today's rulemaking is fully consistent with the Decisions to the Protocol.

One commenter stated that EPA's essential use allowance allocation process and proposed allocations comport with general standards of administrative law. The commenter stated that the proposed rule allocating 2007 allowances clearly meets the non-arbitrariness standard of administrative law that a rulemaking agency must ''examine relevant data'' and that failure to do so could constitute arbitrary decision-making. The commenter specifically commended the use of company-specific stockpile information collected in a follow-up letter sent to companies on May 10, 2006, seeking information under the authority of Section 114 of the CAA. In addition, the commenter stated that the 2007 proposed rule correctly applied the ''one-year operational supply'' provision of Decision XVII/5 and that EPA disclosed FDA's methodology and allowed ample opportunity for public comments. Last, the commenter argued that EPA is required to provide an additional notice and comment opportunity for public comment on any material increase in any company's allocation (e.g. allocating essential use volumes to a company that EPA had proposed would not receive any). The commenter noted that this would include the posting of an explanatory letter from FDA on the docket articulating the reasons for the changes. The commenter requested that EPA provide notice and opportunity for public comment if it is considering allocating any volumes to manufacturers of CFC-albuterol MDIs.

In response to the commenter's request for notice and an opportunity for public comment in the event that EPA issues material changes to a company's allocation, EPA believes that it has reasonably articulated the reasons that two companies are receiving additional allocations in this final rule and that further notice and comment on this issue is unnecessary. As stated in preceding paragraphs, FDA determined, based on additional information received, that essential use allowances should be increased for two companies. With respect to essential use allocations for the manufacture of CFC-albuterol, EPA confirms that it is not allocating any essential use allowances for the manufacture of CFC-albuterol MDIs in the 2007 allocation.

EPA received three comments supporting its timeliness in starting the allocation process and granting allocations in the first quarter of the year to provide for better planning and security of supply.

E. The Transition to Non-CFC MDIs

One commenter provided information showing that HFA products have accounted for a small and largely constant share of the albuterol market over the past four years, and that CFC inhalers represented 92% of total albuterol sales through the first nine months of 2006, according to IMS data. The commenter stated that meeting the demand for CFC-albuterol with the withdrawal of Schering-Plough would require production of CFC-propelled units in 2007 and 2008. The commenter stated that EPA should allocate additional CFC allowances for albuterol production in 2007 and 2008 to allow for an orderly market transition to HFA albuterol. The commenter stated that failure to allocate CFC allowances for albuterol production in 2007 would create marketplace disruption and risk harm to public health, and provided the following justifications to substantiate that claim.

First, the commenter argued that public and private reimbursement has not completely caught up to the changeover to HFA inhalers and gaps remain, particularly in Medicaid and Medicare Part D coverage. Citing IMS data, the commenter maintained that the wholesale prices for HFA albuterol are more than five times higher than for CFC albuterol. A shortage of less-expensive CFC-albuterol MDIs would deprive low-income asthma sufferers of access to inhalers, potentially forcing uninsured patients to seek relief in emergency rooms where treatment may be costly and untimely.

Second, the commenter stated that converting a market from 92% CFC to 100% HFA requires a measured and orderly transition that shifts patients to HFA inhalers while allowing for scale-up of HFA production capacity, education of doctors and patients about the differences between CFC and HFA albuterol, and adaptation to HFA products by pharmacies and insurance companies. The commenter stated that FDA and patient advocates have stressed this point. Further, the commenter argued that a sudden, unexpected unavailability of CFC albuterol might endanger patient health because patients might not have sufficient time to safely transition and because not all formulations of HFA albuterol might be available in sufficient supplies. The commenter also asserted

that HFA inhalers differ from CFC inhalers in taste and delivery feel and that noted that patients may need time to find the most agreeable formulation. Lastly, the commenter stated that pharmacists in states that rely on the Orange Book or the FDA to define ''therapeutic equivalence,'' and do not give discretion to pharmacists to substitute, will not be able to substitute HFA albuterol for CFC albuterol in cases where the prescription provides for CFC albuterol.

Based on input from FDA, EPA disagrees that further allocations of essential use allowances for the manufacture of CFC-albuterol are medically necessary. For 2007 essential use allocations, FDA examined the amount of CFCs available from stocks to manufacture CFC albuterol as well as the supply of HFA albuterol in the marketplace and has determined that there is not a medical need to allocate allowances for CFC albuterol. According to FDA, based on information that FDA is receiving from HFA manufacturers, HFA manufacturers currently have the ability to produce enough HFA-albuterol MDIs to meet total market demand for albuterol MDIs.

EPA and FDA understand that patients may incur additional costs to purchase albuterol inhalers as the market transitions to HFA MDIs. For example, EPA and FDA recognize that patients covered by medical insurance may encounter higher co-payments to purchase HFA albuterol. However, patient assistance programs exist to assist patients with the increased costs. For low-income patients, these programs include free and discounted medicines. To assist patients facing higher co-pays associated with the increased costs of the HFA MDIs, programs such as coupons and discounted HFA MDIs are being made available through physicians, at pharmacies, and at individual manufacturers' Web sites.

Advocacy and non-profit groups have been pursuing education and outreach efforts in preparation for the December 31, 2008 phaseout of CFC-albuterol inhalers. They understand that educating doctors, patients, and pharmacies is paramount. FDA selected December 31, 2008, as the phaseout date largely because it provided sufficient time for the transition to HFA MDIs to occur. This time allows for patients to meet with their doctors and for their doctors to discuss the change to HFA MDIs. FDA is monitoring the supply of albuterol closely and does not anticipate any shortages in 2007.

One commenter supported EPA's proposal to allocate no essential use allowances for 2007 for single-moiety albuterol CFC MDIs because satisfactory alternatives are available. The commenter asserted that the December 31, 2008 effective date of non-essentiality of CFC-albuterol MDIs is overly conservative. Two CFC-free alternatives to CFC-albuterol MDIs have been on the market for several years. In addition, the commenter stated that it is now clear that the bulk of the transition to CFC-free albuterol will occur well before 2008, provided that the companies' efforts to transition the market are not undercut. The commenter noted that two additional CFC-free alternatives to CFC-albuterol MDIs have been introduced into the market since FDA began its rulemaking process to remove the essential use designation for albuterol MDIs. According to the commenter, FDA has determined that approximately 40 percent of albuterol MDIs produced in 2006 used HFA–134a as their propellant and FDA anticipates that this will grow to 60 percent in 2007 and 80 percent in 2008. The commenter stated its belief that this estimate is overly conservative given that Warrick Pharmaceuticals, which currently produces approximately 70 percent of the albuterol CFC MDIs sold in the US, announced plans to cease manufacture of CFC inhalers in early 2007 and plans to transition patients to its HFA alternative.

The commenter also noted that the only remaining risk to the successful transition of the albuterol MDI market is that those companies that do not have albuterol CFC-free alternatives on the market, and therefore have no interest in seeing the transition successfully concluded, may see the transition as an opportunity to gain temporary market share. The commenter argued that these companies could capitalize on patients who are displeased with the new prescriptions, and with adjustments to the inhalers' ''taste and feel,'' associated with alternatives.

One commenter recommended that EPA state that CFC albuterol MDIs are not essential in the U.S. under Montreal Protocol criteria and that new CFC production for such uses is not necessary. The commenter noted that four CFC-free albuterol MDIs have been approved by FDA and are now on the market and that numerous patient assistance programs ensure that low-income and uninsured patients can afford these medications. Therefore, the commenter notes, CFC-albuterol MDIs are no longer essential under the Decision IV/25 criterion and essential use allowances may no longer legally be allocated for that use because technically and economically feasible alternatives are available. The commenter believes that, at a minimum, EPA should state that new production of CFCs for albuterol MDIs is *per se* not necessary.

Similarly, another commenter noted that the preamble to Decision XVIII/7 states the need for Parties to limit essential use allocations. This commenter cites Decision IV/25, which states that CFCs for use in MDIs shall not qualify as essential ''if technically and economically feasible alternatives or substitutes are available,'' and the TEAP report concludes that ''technically satisfactory alternatives'' to CFC-based MDIs are available for short-acting beta-agonists.

In 2005, FDA issued a final rule removing the essential use designation for CFC-albuterol MDIs as of December 31, 2008 (70 FR 17168). FDA based this decision on a comprehensive analysis that addressed, among other issues, the availability and convenience of non-ODS alternatives. FDA determined that December 31, 2008, was an appropriate date because it believed that adequate production capacity and supplies of HFA albuterol would be available to meet patient need. So, while alternatives to CFC-albuterol MDIs were available at that time, the supply and the capacity of manufacturers to produce sufficient amounts of HFA MDIs to meet the demand for albuterol were not yet adequate. A date of December 31, 2008 was chosen to provide time for a smooth and successful transition to occur and to prevent a shortage in the market that would affect patients' ability to receive albuterol. That transition is well underway, but some production of CFC-albuterol remains necessary and albuterol remains listed in 21 CFR 2.125(e).

One commenter stated that based on current market conditions, it believes that the total supply of albuterol MDIs (both HFA and CFC inhalers) in the market should continue to meet demand during the transition to HFA. The commenter noted that it has significantly increased the amount of HFA albuterol inhalers that it produces, and that it is in the position to increase its supply further if the need arises. It further noted that based on publicly available data, it appears that another HFA albuterol inhaler manufacturer has also increased supply of its HFA albuterol inhaler. Lastly, the commenter stated that its communications from FDA indicate that FDA, based on discussions with all manufacturers of albuterol inhalers, is not anticipating near-or medium-short-term shortages of

albuterol MDIs. In this regard, the commenter argued that there is no need for incremental CFC-based albuterol MDIs beyond the previously approved 2006 CFC allocations to meet overall albuterol demand in the United States.

Two commenters supported EPA's proposed allocation and asserted that a gradual transition from CFC albuterol to HFA albuterol would benefit patients. One commenter stated EPA correctly concluded, based on the availability of alternatives, that CFCs for albuterol MDIs are not necessary, as defined by Section 604(d)(2) of the Clean Air Act; and that the proposed allocations would benefit patients by smoothing the transition to alternatives.

One commenter supported the proposed allocation because it provided for a timetable that would enable CFC albuterol supplies to be drawn down while ensuring a steady, reliable supply of HFA product. The commenter stated that a smooth transition requires a gradual conversion of the albuterol market to HFAs and that this transition should be completed sufficiently in advance of December 31, 2008. The commenter noted that an abrupt transition would have potential negative health impacts, present an onerous administrative burden on providers and pharmacies, and waste any potential for transition to improve disease management.

Both commenters cautioned the Agency about the negative health outcomes potentially associated with patients transitioning several times between CFC and HFA inhalers or using both products at once. One commenter stated that specific benchmarks can minimize confusion in pharmacies and that an efficient phase-out period with consistent downward pressure on the availability of CFC MDIs can prevent these problems. The commenter also suggested that nine months would be an appropriate conversion period for CFC and HFA products to coexist in the market.

One commenter noted that the four HFA albuterol MDIs on the market are all different formulations, while the CFC albuterol MDIs were all similar. The commenter asserted that this variety will benefit patients by allowing them to find a formulation that works best for them and to avoid formulations to which they are allergic. The commenter noted that some of the HFA MDIs also have new features that were absent in the CFC models and that the production variety improves security of supply. The commenter also stated that the proposed allocations sent a consistent and appropriate signal to all affected constituencies that the Government is serious about the albuterol transition, which is prompting patient education and outreach.

III. Allocation of Essential Use Allowances for Calendar Year 2007

With this action, EPA is allocating essential use allowances for calendar year 2007 to the entities listed in Table 1. These allowances are for the production or import of the specified quantity of Class I controlled substances solely for the specified essential use.

TABLE 1.—ESSENTIAL USE ALLOWANCES FOR CALENDAR YEAR 2007

Company	Chemical	2007 Quantity (metric tons)
(i) Metered Dose Inhalers (for oral inhalation) for Treatment of Asthma and Chronic Obstructive Pulmonary Disease		
Armstrong Pharmaceuticals	CFC–114 (production of epinephrine MDIs only)	22.4
Inyx (Aventis)	CFC–11 or CFC–12 or CFC–114	39.6
3M Pharmaceuticals	CFC–11 or CFC–12 or CFC–114	65.0
Wyeth	CFC–11 or CFC–12 or CFC–114	40.0

IV. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order (EO) 12866 (58 FR 51735, October 4, 1993), this action is a ''significant regulatory action'' because it raises novel legal or policy issues. Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under EO 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action.

EPA prepared an analysis of the potential costs and benefits related to this action. This analysis is contained in the Agency's Regulatory Impact Analysis (RIA) for the entire Title VI phaseout program (U.S. Environmental Protection Agency, ''Regulatory Impact Analysis: Compliance with Section 604 of the Clean Air Act for the Phaseout of Ozone Depleting Chemicals,'' July 1992). A copy of the analysis is available in the docket for this action and the analysis is briefly summarized here. The RIA examined the projected economic costs of a complete phaseout of consumption of ozone-depleting substances, as well as the projected benefits of phased reductions in total emissions of CFCs and other ozone-depleting substances, including essential use CFCs used for metered-dose inhalers.

B. Paperwork Reduction Act

This action does not impose any new information collection burden. The recordkeeping and reporting requirements included in this action are already included in an existing information collection burden and this action does not make any changes that would affect the burden. However, the Office of Management and Budget (OMB) has previously approved the information collection requirements contained in the existing regulations at 40 CFR 82(a) under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2060–0170, EPA ICR number 1432.25. A copy of the OMB approved Information Collection Request (ICR) may be obtained from Susan Auby, Collection Strategies Division; U.S. Environmental Protection Agency (2822T); 1200 Pennsylvania Ave., NW., Washington, DC 20460 or by calling (202) 566–1672.

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.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impact of today's rule on small entities, small entities are defined as: (1) Pharmaceutical preparations manufacturing businesses (NAICS code 325412) that have fewer than 750 employees; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise that is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any significant adverse economic impact on small entities, since the primary purpose of the regulatory flexibility analyses is to identify and address regulatory alternatives ''which minimize any significant economic impact of the proposed rule on small entities.'' 5 U.S.C. 603 and 604. Thus, an agency may conclude that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, or otherwise has a positive economic effect on all of the small entities subject to the rule. This rule provides an otherwise unavailable benefit to those companies that are receiving essential use allowances. We have therefore concluded that today's final rule will relieve regulatory burden for all small entities.

D. 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 to State, local, and tribal governments, in the aggregate, or to 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.

Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed a small government agency plan under section 203 of the UMRA. 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, since it merely provides exemptions from the 1996 phase-out of Class I ODSs. Similarly, EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments, because this rule merely allocates essential use exemptions to entities as an exemption to the ban on production and import of Class I ODSs.

E. 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.''

This final rule does not have federalism implications. It 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. Thus, Executive Order 13132 does not apply to this rule.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' This final rule does not have tribal implications, as specified in Executive Order 13175. Today's rule affects only the companies that requested essential use allowances. Thus, Executive Order 13175 does not apply to this rule.

G. 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 E.O. 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 final 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.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This rule is a not ''significant energy action'' as defined in Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The rule affects only the pharmaceutical companies that requested essential use allowances.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Public Law 104–113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in 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 final rule does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

J. Congressional Review Act

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. Therefore, 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 rule is not a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective June 12, 2007.

V. 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 judicial proceedings brought to enforce those requirements.

VI. Effective Date of This Final Rule

Section 553(d) of the Administrative Procedures Act (APA) generally provides that rules may not take effect earlier than 30 days after they are published in the **Federal Register**. Today's final rule is issued under section 307(d) of the CAA, which states, ''The provisions of section 553 through 557 * * * of Title 5 shall not, except as expressly provided in this subsection, apply to actions to which this subsection applies.'' Thus, section 553(d) of the APA does not apply to this rule. EPA nevertheless is acting consistently with the policies underlying APA section 553(d) in making this rule effective June 12, 2007. APA section 553(d) provides an exception for any action that grants or recognizes an exemption or relieves a restriction. Because today's action grants an exemption to the phaseout of production and consumption of CFCs, EPA is making this action effective immediately to ensure continued availability of CFCs for medical devices.

List of Subjects in 40 CFR Part 82

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

Dated: June 6, 2007.

Stephen L. Johnson,

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 82.8 is amended by revising the table in paragraph (a) to read as follows:

§ 82.8 Grants of essential use allowances and critical use allowances.

(a) * * *

TABLE I.—ESSENTIAL USE ALLOWANCES FOR CALENDAR YEAR 2007

Company	Chemical	2007 Quantity (metric tons)
(i) Metered Dose Inhalers (for oral inhalation) for Treatment of Asthma and Chronic Obstructive Pulmonary Disease		
Armstrong Pharmaceuticals	CFC–114 (production of epinephrine MDIs only)	22.4
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3M Pharmaceuticals	CFC–11 or CFC–12 or CFC–114	65.0
Wyeth	CFC–11 or CFC–12 or CFC–114	40.0

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