

where the synthesized or separated component is not stored prior to formulation. Typically, coatings include products described by the following North American Industry Classification System (NAICS) codes, code 325510, Paint and Coating Manufacturing, code 325520, Adhesive and Sealant Manufacturing, and code 325910, Ink Manufacturing.

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 82

[EPA-HQ-OAR-2006-0158; FRL-8227-4]

RIN 2060-AN29

### Protection of Stratospheric Ozone: Allocation of Essential Use Allowances for Calendar Year 2006

**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 2006. Essential use allowances enable a person to obtain controlled class I ODSs as part of an exemption from the regulatory ban on the production and import of these chemicals that 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 1,002.40 metric tons (MT) of chlorofluorocarbons (CFCs) for use in metered dose inhalers for 2006.

**DATES:** *Effective Date:* This final rule is effective October 4, 2006.

**ADDRESSES:** EPA has established a docket for this action under Docket ID No. EPA-HQ-OAR-2006-0158. All documents in the docket are listed on the [www.regulations.gov](http://www.regulations.gov) Web site. Although listed in the index, some information is not publicly available, e.g., confidential business information 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](http://www.regulations.gov) or in hard copy at the Air Docket, EPA/DC, EPA West, Room B102, 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.

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#### SUPPLEMENTARY INFORMATION:

##### Table of Contents

- I. Basis for Allocating Essential Use Allowances
  - A. What are essential use allowances?
  - B. Under what authority does EPA allocate essential use allowances?
  - C. What is the process for allocating essential use allowances?
- II. Response to Comments
  - A. EPA Should Not Allocate Essential Use Allowances
  - B. The Proposed Level of Allocations Is Incorrect
  - C. Consideration of Stocks of CFCs in the Allocation of Essential Use Allowances
  - D. Comments on the Rulemaking Process and Timing
  - E. EPA May Not Allocate Allowances to Companies That Fail To Demonstrate Research and Development of Alternatives
  - F. Transition to Non-CFC Metered Dose Inhalers
- III. Allocation of Essential Use Allowances for Calendar Year 2006
- IV. Statutory and Executive Order Reviews
  - A. Executive Order 12866: Regulatory Planning and Review
  - B. Paperwork Reduction Act
  - C. Regulatory Flexibility Act
  - D. Unfunded Mandates Reform Act
  - E. Executive Order 13132: Federalism
  - F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
  - G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks
  - H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use
  - I. National Technology Transfer and Advancement Act
  - J. Congressional Review Act
  - V. Judicial Review
  - VI. Effective Date of this Final Rule

## I. Basis for Allocating Essential Use Allowances

### A. What are essential use allowances?

Essential use allowances are allowances to produce or import certain ozone-depleting substances (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<sup>1</sup> of ODSs. The elimination of production and consumption of class I ODSs is accomplished through adherence to phaseout schedules for specific class I ODSs,<sup>2</sup> which include chlorofluorocarbons (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 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

<sup>1</sup> “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).

<sup>2</sup> Class I ozone depleting substances are listed at 40 CFR part 82 subpart A, appendix A.

from existing stocks of banked or recycled controlled substances, also bearing in mind the developing countries' need for controlled substances."

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

Title VI of the Clean Air 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 metered dose inhalers (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 Protocol, under Decision XV/8, additionally allow 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 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 exemption 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?*

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 Protocol's Technology and Economic Assessment Panel (TEAP) evaluates the nominated essential uses and makes recommendations to the Protocol Parties. The Parties make the final decisions on whether to approve 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 this final rule were first nominated by the United States in January 2004.

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 to each eligible entity. Under the Act and the Protocol, EPA may allocate essential use allowances in quantities that together are below or equal to the total amount approved by the Parties. EPA will not allocate essential use allowances in amounts higher than the total approved by the Parties. For 2006, the Parties authorized the United States to allocate up to 1,100 metric tons (MT) of CFCs for essential uses. In a notice of proposed rulemaking published in the **Federal Register** on April 11, 2006 (71 FR 18262), EPA proposed to allocate 1,002.40 MT.

**II. Response to Comments**

EPA received comments from ten entities on the proposed rule. Two commenters, both members of the general public, did not support an exemption as a general matter, one commenter indicated that his company received too few allowances to adequately protect patient safety, four

commenters believed that EPA allocated more allowances than were necessary given the presence of stocks of CFCs in the United States, one commenter indicated that the Agency should not increase one company's allocations at the expense of a second company and should instead increase the total levels of allocations to accommodate any shortfalls. Lastly, one commenter believed that there is no downside to allocating the maximum number of allowances possible because companies only expend those allowances that they need. The comments are addressed in more detail below.

*A. EPA Should Not Allocate Essential Use Allowances*

One commenter wrote that non-CFC MDIs should be developed. This commenter also expressed a belief that a particular pharmaceutical company, Schering-Plough, should not be permitted to produce CFC MDIs since CFCs are banned. Additionally, this commenter feels that asthma would not be as serious a problem if the U.S. Government stopped burning national forests, parks, and wildlife areas. Another commenter expressed the opinion that the 1,002.40 MT of CFCs are not necessary for the manufacture of MDIs for the treatment of asthma and COPD. According to this commenter, skin cancer is not a suitable alternative to the lack of innovation by the companies that want to use CFCs.

Another commenter also did not believe that Schering-Plough should receive an essential use allocation. The commenter stated that the cornerstone of the temporary essential use process is that production of CFCs for MDIs should be allowed only until companies are able to develop and bring to market adequate non-CFC alternatives for patients. The commenter noted that TEAP has expressed a strong concern that "companies continue to request essential use quantities for CFCs when they also manufacture HFA MDI alternatives for salbutamol," and that Schering Plough has had an approved non-CFC Albuterol MDI, Proventil(r), on the market for a decade. Therefore, the commenter believes that no legal basis exists for allocating essential use CFCs to Schering-Plough.

FDA, in consultation with EPA, has determined that 1,002.40 MT of CFCs are necessary to meet the demand for 2006 MDI manufacturing. As alternatives become available, FDA will be in a position to propose delisting of essential uses in a manner that is protective of patient safety. EPA appreciates the commenter's interest in the causes of asthma and reiterates that

FDA's determination is made in accordance with protecting public health.

Delisting of CFC MDIs will proceed in accordance with the 2002 FDA rule establishing a mechanism for removing essential uses from the list in 21 CFR 2.125(e), published in the **Federal Register** on July 24, 2002 (67 FR 48370) (corrected at 67 FR 49396 and 67 FR 58678). Delisting of albuterol CFC MDIs is addressed specifically in the FDA rule published in the **Federal Register** on April 4, 2006 (70 FR 17168). Under this rule, CFC albuterol MDIs will no longer be essential as of the end of 2008. In addition, FDA is in the process of examining the remaining essential use products to determine if and when they might no longer require an essential use designation. The U.S. is making substantial progress in the phasedown of exempted CFC production. For example, in 2005 the Agency allocated about 1,750 MT of CFCs while in this action for 2006 the Agency is only allocating 1,002.40 MT of CFCs.

Schering-Plough manufactures a product which, as of 2006, is still essential to the U.S. supply of albuterol MDIs for treatment of asthma and COPD. With regard to the comment regarding the TEAP 2005 Progress Report, while the TEAP did express concerns "that companies continue to request essential use quantities for CFCs when they also manufacture [HFA] MDI alternatives for [albuterol]," it nevertheless recommended an essential use exemption for the United States that included CFCs intended for Schering-Plough, and this exemption was approved by the Parties.

#### *B. The Proposed Level of Allocations is Incorrect*

One commenter stated that unless EPA increases the essential use allocation for CFC propellants for Armstrong Pharmaceuticals, the only company with idle CFC albuterol production capacity, there will be a shortage of albuterol MDIs as early as June or July of 2006 because a European firm, IVAX, is no longer providing some 12 million units of albuterol inhalers to the U.S. market. Therefore, the commenter requested that the 2006 essential use allowances granted to Armstrong be increased from the proposed 147.50 MT to 347.50 MT. The commenter noted that Medical Technical Options Committee (MTOC) recommended that 180 MT be added to the U.S. allocations for 2006 if CFC MDIs were not imported from Europe in 2006. A second commenter noted that EPA proposed to allocate 1,002.40 MT of CFCs for MDIs whereas the Parties to

the Montreal Protocol authorized 1,100 MT and suggested that the 2006 allocations could be raised to the upper limit established in the Decision due to the IVAX situation. This commenter indicated that because in the past MDI producers have only utilized the rights that they felt were critical to meet evolving supply/demand, there is limited risk associated with the full allocation of available rights and notes that because excess CFCs will need to be destroyed, essential use inventories will actually become a financial liability and producers will avoid overproduction of CFC MDIs and excessive purchase of CFC propellant.

One commenter believes that the Agency does not fully understand the restrictions on the availability of stocks of CFCs and that EPA's inaccurate understanding of the matter led to proposed allocations that are too low. They believe that misleading information in the May 2005 TEAP Progress Report on the availability for the sale of GlaxoSmithKline (GSK)'s excess pre-1996 CFC propellant has led FDA and EPA to assume that 605 MT of pre-1996 CFCs held by GSK would be available to all potential users even though GSK will only sell these CFCs to four companies that do not have a need for the material. The commenter also believes that in determining the size of Armstrong's allocation, the Agency assumed that Armstrong could obtain additional CFCs from Schering-Plough.

Two commenters are of the opinion that Armstrong Pharmaceuticals' request for an additional 180 MT of CFCs should be denied and recommended that Armstrong not be granted any CFC allocations, including the 147.50 MT granted in the proposed rulemaking. Based on figures provided by Armstrong Pharmaceuticals, the commenter claims that Armstrong Pharmaceuticals has more than enough CFCs to serve its market share without receiving any allocation for 2006. To support this claim, the commenter stated that Armstrong Pharmaceuticals may manufacture as many as 6.4 million MDIs in 2006, requiring 147 MT of CFCs, which can be met by their stockpile of at least 195 MT of CFCs (based on the difference between the CFCs needed to manufacture 3.29 million MDIs in 2005, and the amount of CFCs purchased by Armstrong in 2005).

One commenter indicated it believed Armstrong Pharmaceuticals made several inaccurate and misleading statements during the April 21, 2006 public hearing. These include the company's assertion, to support its request for an increased 2006 allocation,

that the European Community did not allocate any CFCs for the use in the production of albuterol MDIs, and therefore that 21.4 million imported albuterol MDIs were lost to the U.S. market. According to the commenter, IVAX never supplied more than 14 million CFC MDIs to U.S. markets. In addition, the commenter also stated that in late 2005, the European Commission allocated 180 MT of CFCs to IVAX for production of albuterol MDIs to be exported to the U.S. The commenter wished to correct Armstrong Pharmaceuticals' claim that the 605 MT of GSK's pre-1996 CFCs is only available to four companies that no longer require CFCs for MDIs. This commenter states that these companies require CFCs for the production of essential MDIs. A second commenter indicated that GSK did not provide any misleading information concerning the sale of its pre-1996 CFC supply. A third commenter indicated that her company did have a need for, and purchased, CFCs from the GSK pre-1996 stockpile.

EPA believes that the underlying premise of the essential use exemption program is to provide for the continued production and consumption of CFCs needed to ensure patient safety. EPA concurs with the comment that historically, companies have only used the allowances they needed and that production of CFCs in excess of the amount needed by a company would create a liability in that such material would have to be destroyed or used by another essential use. However, allocations are based on determinations of medical necessity.

Since the October 2005 determination by FDA, fewer albuterol CFC MDIs have entered the market because IVAX stopped production. The market has also experienced an increase in the number of HFA MDIs. In making its determination on the amount of CFCs that are medically necessary, FDA looks at factors such as the number of medical device units required to meet patient demand and the amount of CFCs already owned by MDI manufacturers. FDA informs us that they have been closely monitoring the albuterol supply in response to spot shortages, particularly of albuterol CFC MDIs, in late winter and spring of 2006. Based on up-to-date information, there is an adequate supply of albuterol MDIs to meet patient needs in the U.S., as the production capacity for the albuterol HFA MDIs has increased substantially in the first half of 2006 and is expected to continue to increase. While albuterol HFA MDI capacity is expected to continue to increase throughout 2006 and beyond, FDA has not determined a

reduction from the proposed allocations for albuterol MDIs because the projections FDA has heard indicate that there will be a continuing need for albuterol CFC MDIs through all of 2006. FDA is also concerned that some of the projections are not sufficiently reliable to provide a basis for a determination that could result in shortages of this necessary drug, if expectations are not met. Therefore, EPA is not altering the proposed allocation of allowances in this final rule to either increase allocations or decrease them.

EPA was fully aware of the terms regarding the resale of the 605 MT of CFCs previously owned by GSK and was provided with a copy of the contract. EPA shared the terms of the contract with FDA. Further, as EPA has stated previously, both agencies only consider amounts of stocks owned by a given MDI manufacturer in determining the appropriate level of essential use allocation. Therefore, stocks not owned by an MDI manufacturer and future potential commercial arrangements for the sale of such stocks did not affect the allocations.

In regard to concerns about the increased cost, see section II.F of this preamble document on the transition to CFC alternatives.

One commenter argued that EPA should raise the total level of allocations and pointed to the terms of sale of 605 MT of GSK's pre-1996 CFC inventory as a reason to support such an action. This commenter argues that the terms of sale have made it difficult to determine both the level and distribution of CFC allocations, which could cause concern about how fluid the market may be at responding to patients' needs. The commenter further points to the potential that some producers involved in the CFC-to-HFA propellant transition may choose to redirect their production away from CFC-based products, while not releasing unutilized allocation rights to other producers for competitive reasons, thus causing further restrictions on availability of CFCs.

As described above, EPA was fully aware of the restrictions on the resale of the 605 MT formerly owned by GSK. In light of the fact that none of that material may be resold to the essential use companies that manufacture singly moiety albuterol MDIs, the concerns of the commenter regarding the difficulty of determining "both the level and distribution of CFC allocations" and "how fluid the market may be at responding to patients' needs" would not apply to those companies that are receiving exemptions to manufacture single moiety albuterol MDIs because these companies are not permitted to

purchase any of the 605 MT to which the commenter is referring. Further, the Agency looks at holdings of CFCs stocks on a manufacturer-by-manufacturer basis. Only those quantities owned by an MDI manufacturer are assessed in determining their overall allocation needs. Thus, if the terms of resale on the GSK material contributed to some difficulties in the fluidity of the CFC propellant market, it should have no bearing on meeting patient demand for MDIs since these materials are excluded from the Agency's assessment until they are owned by an essential use company.

The commenter's second concern that companies that are transitioning to an HFA-based alternative will not be inclined to sell or otherwise make their allowances available to a company that is still producing a product in a CFC format is immaterial. If a company is increasing production of its HFA product and decreasing its CFC product at the same rate, there is no need for a second company to increase its production of CFC product since the total number of units on the market remains the same and is sufficient to protect patient safety.

One commenter stated that EPA must fully consider how the CFC allocations will affect moieties for which there are no alternatives—i.e., that a too-generous allocation for CFC albuterol MDIs that are being phased out could result in a backlash against the remaining essential use products, some of which do not yet have alternatives. The commenter noted that the 2006 allocation is significantly reduced from what EPA or the U.S. Government requested from the international community, yet albuterol comprises the majority of the allocation. To that end, the commenter encourages EPA to consider whether the allocation in the proposed rule takes into account the rapidly changing market for albuterol, noting that the allocation could be based on 6-to-12-month-old information, and asks the Agency to ensure that the moieties that really need CFCs will have CFCs until they approach the reformulation stage. A second commenter concurred with this sentiment and expressed the opinion that it is in the best interests of patients and the environment if the availability of essential use CFCs is preserved for the production of essential MDIs for which alternatives are not yet available but are under development. This second commenter stated that recent albuterol shortages illustrate the potential disruption to patient care if medication is unavailable and further stated that this risk would be significantly exacerbated in a situation where non-CFC alternatives were not available.

Therefore, the commenter recommends that, rather than allocate any volumes for Schering-Plough and Armstrong Pharmaceuticals, EPA hold those volumes for a possible emergency allocation later in the year for those companies not manufacturing single-moiety albuterol MDIs.

EPA and FDA carefully consider the requirements for all essential uses of CFCs, including those non-albuterol MDIs that may continue to be essential uses beyond 2008. The domestic and international consideration of the essentiality of a product is technically based. Most of the 2006 allocation is for albuterol MDIs, consistent with both domestic and international technical reviews. At the time of proposal of the 2006 essential use rule, EPA and FDA were not aware of any current market conditions that would alter the CFC requirements for 2006 essential uses. Further, as described earlier in this document, more recent information has not indicated that there is a significant change in requirements for 2006. With the coming December 2008 ban on the sale of single moiety albuterol CFC MDIs, EPA and FDA anticipate that there may be a rapidly changing market that would affect the 2007 essential use allocation. The Agencies will monitor the situation and make any adjustments that are necessary in the 2007 proposed and final rules.

EPA considered and rejected the commenter's suggestion that EPA hold allowances proposed for Schering-Plough and Armstrong Pharmaceuticals as an emergency reserve for non-albuterol products. EPA received a determination from FDA as to the volume of CFCs required for non-albuterol products and FDA has informed us that those volumes, along with stocks held by the manufacturers, are sufficient to protect public health. Additional allowances are not medically necessary. Since allowances expire on December 31, 2006, any recommended "emergency" allowances would have to be expended by that date. As previously stated, there is no anticipated shortage of 2006 CFCs for non-albuterol uses. Lastly, comments submitted by companies that have non-albuterol products also indicate that the levels proposed by EPA are sufficient for their 2006 needs. Therefore, EPA does not believe it is necessary to create an emergency reserve for non-albuterol uses with 2006 allowances.

One commenter indicated that in granting allowances, EPA should not increase one company's allocation at the expense of a second company's, but instead any additional allocations should come from the difference

between the amount authorized by the Parties, 1,100 MT, and the amount allocated by the Agency, 1,002.40 MT. This commenter also stated that it is satisfied with its proposed 2006 allocation and that it represents the minimum amount required to meet the market demand for the commenter's product. A second commenter indicated satisfaction with its proposed allocation.

In this action, EPA is not changing the 2006 allocations to individual companies, or in total, from the amounts proposed.

### C. Consideration of Stocks of CFCs in the Allocation of Essential Use Allowances

One commenter urged EPA to clarify that "operational supply" encompasses not only the amount of CFCs needed to meet MDI demand for a particular year, but also a "safety stock." This commenter believes a stock of up to 12 months of forward demand is prudent, given that there is now a single supplier in the U.S. and a long lead time associated with revalidating an interrupted plant, and that this is consistent with the view of the Aerosols and Miscellaneous Uses Technical Options Committee (ATOC) expert panel.<sup>3</sup> The commenter states that this view has also been adopted by the TEAP, which recommended to the Parties that companies be permitted to maintain a one-year safety stock of CFCs.<sup>4</sup>

In addition, this commenter suggests that EPA take into account blend requirements and only count stock blended in the needed proportion when calculating the safety stock limit. The commenter notes that the pre-1996 stockpile recently made available by GlaxoSmithKline comprises only CFC-11 and CFC-12, but to the extent that the commenter's company sources its needs from that stock, it will be unusable if it is not supplemented by CFC-114. This commenter also believes that EPA should take into account a company's need to maintain a safety stock for each of its foreign affiliates, as no excess supply is maintained at European production sites or certain other affiliates. The commenter explained that the European Commission takes into account a company's global supply when determining allocations, forcing companies to maintain an operational supply for their European facilities as

well as their U.S. facilities. This situation also results in the expenditure of two allowances for each metric ton of CFCs transferred from U.S. to European facilities.

This commenter notes that the conversion of safety stock to "just in time" supply will be made as the end date for the company's transition becomes clearer. Given the cost of destruction and the "point of sale" ban that will render the company's stockpiles of no use when its CFC products are deemed non-essential, this commenter states that it has every incentive to avoid excess stockpiles.

In assessing the amount of new CFC production required to satisfy 2006 essential uses, EPA and FDA applied the terms of Decision XVII/5 including provisions on stocks of CFCs that indicate Parties should allocate such that manufacturers of MDIs maintain no more than a one-year operational supply. FDA's current practice is to first calculate the quantity of CFCs that a manufacturer needs for MDIs in the year in question and then subtract from that quantity any CFC stocks owned by that MDI manufacturer exceeding a one-year operational supply. The remainder, if a positive number, is the quantity of newly produced or imported CFCs needed by that manufacturer. Consistent with the language of Decision XVII/5, FDA has informed EPA that it considers the quantity of CFCs owned by each manufacturer, rather than the total supplies owned by all entities. EPA does not read Decision XVII/5 as endorsing a safety stock in excess of the one-year operational supply specifically mentioned in the Decision.

EPA's proposed allocation did not take the blend of CFCs into account in determining the size of a manufacturer's stocks and the ensuing amount of new CFCs required. EPA does not currently collect data on the specific CFCs that comprise the stocks owned by the MDI manufacturer. EPA agrees that it would be reasonable to take into account the type of CFC needed for MDI production if EPA had such data.

Two commenters indicated that in determining a company's pre-allocation "operational supply," EPA and FDA should count all stocks owned or controlled by a company, including stocks at its production facility, in transit, on order, or stored off-site.

FDA evaluated stocks owned by an MDI manufacturer, regardless of the physical location of the material, in making its determination.

Two commenters stated that in order to effectively implement Decision XVII/5, FDA and EPA should evaluate the level of stockpiles held by companies as

of the end of 2005, or as of January 2006. In determining how much a company needs to maintain a "one-year operational supply," EPA and FDA should consider how much a company needs to serve markets during the year and maintain a reasonable safety reserve. The starting point for determining this amount could be the amount of CFCs a company used in the previous year, which could be modified based on the company's circumstances. They further state that EPA should only allocate CFCs to a company if the company's one-year operational supply need is greater than its pre-allocation operational supply. The commenter defines "operational supply need" as the amount the company needs to "serve its markets during the current year" plus a reasonable safety reserve, not to exceed 12 months. The commenter defines "pre-allocation operational supply" as all stocks owned or controlled by a company. Additionally, with regard to the safety net, a 12-month level would be excessive for products with an established phaseout date and where the market is transitioning to non-CFC products. According to one of the commenters, the *U.S. Reporting Accounting Framework* reported that 1,911 MT of CFCs were "on hand" at the end of 2005. With the addition of 1,000 MT of pre-phase out CFCs (398.6 MT reported by the U.S. Accounting Framework and 605 MT made available by GSK), the commenter asserts that almost three times more than the 1,171 MT of CFCs used in 2005 were available for use in MDIs as of the end of 2005.

A third commenter indicated that allowable operational supply should be determined based on the average carried over the course of a year, as opposed to year-end supply, which may appear excessive given the fact that the production of CFCs-11 and -12 occur only during August and this commenter receives a full year's supply at that time.

With regard to the first two commenters' concern on the timing for EPA's determination, the Agency refers readers to section II.D of this preamble on the essential use process. EPA and FDA do not concur with the commenter that a safety net of 12 months is excessive for those products where the market is transitioning. EPA notes that the product in question (albuterol CFC MDI) is not set to be phased out until December 31, 2008. Given that the final transition date is more than a year away, it still makes sense to factor in a "one-year operational supply" at this time. EPA believes this comment may be more pertinent to 2007 and 2008, the last years of the transition.

<sup>3</sup> See "1998 Report of the Aerosols, Sterilants, Miscellaneous Uses, and Carbon Tetrachloride Technical Options Committee," pp. 58-59.

<sup>4</sup> See "UNEP Technology and Economic Assessment Panel April 1998 Report" at p. 16, sec. 1.2.4.

As stated above, FDA first calculates the quantity of CFCs that a manufacturer needs for MDIs in the year in question and then subtracts from that quantity any CFC stocks owned by that manufacturer in excess of a one-year operational supply. FDA evaluates data provided to EPA before and during the rulemaking process which may include stocks data collected midyear, as was the case for the 2006 rulemaking. Those stocks include all materials owned by a manufacturer. Consistent with the language of Decision XVII/5, FDA has informed EPA that it considers the quantity of CFCs owned by each MDI manufacturer, rather than the total supplies owned by all entities. EPA notes that some of the stocks one of the commenters points to in the U.S. Accounting Framework are not owned by MDI manufacturers. EPA reminds commenters that the U.S. Accounting Framework captures data at the aggregate level but that allowance allocation determinations are company-specific.

In determining what authorization of new production is "necessary for use in medical devices" under section 604(d)(2) of the CAA, FDA calculates the quantity of CFCs needed to produce an adequate supply of medical devices for use by patients, or other end users, in the relevant year. FDA does not consider the increase of a manufacturer's year-end stock of CFCs to be "necessary" for purposes of section 604(d)(2). FDA has informed EPA that, in accordance with this reading of section 604(d)(2) of the CAA, FDA will not make a determination that any newly produced CFCs are needed, if the resulting allocation would reasonably be expected to result in the MDI manufacturer having a larger stock of CFCs at the end of a relevant year than it had at the beginning of that year. FDA has provided the following examples of its current method of arriving at a determination of the quantities of CFCs needed for a given year:

- Manufacturer A will have 100 MT of CFCs in stocks at the beginning of a year. 50 MT are required to produce the MDIs needed in that year. FDA would determine that no additional CFCs are needed because Manufacturer A will have a one-year supply of CFCs in stock at the end of the year.

- Manufacturer B will have 100 MT of CFCs in stocks at the beginning of a year. 150 MT are required to produce the MDIs needed in that year. FDA would determine that Manufacturer B's allocation should only be 150 MT, as determinations made by FDA are not

intended to increase stocks of CFCs through the allocation process.

Both examples assume that the necessary quantities of CFC-containing MDIs remain constant. FDA has informed EPA that as the manufacture, and capacity for manufacture, of non-ODS alternatives, including albuterol HFA MDIs, increases, it takes those increases into consideration in making its determination under section 604(d)(2) of the CAA, and will continue to do so. EPA agrees that FDA's approach to determining the necessary quantity of newly produced or imported CFCs for the manufacture of essential MDIs is reasonable, appropriate, and consistent with relevant provisions of the Parties' Decisions, the Montreal Protocol, and the CAA.

#### *D. Comments on the Rulemaking Process and Timing*

Three commenters expressed the opinion that EPA has not adequately supported its proposed essential use allocations for 2006 because EPA could not have adequately taken into account Decision XVII/5 given the timing of the proposed rule. Since Decision XVII/5 was adopted on December 16, 2005 at the 17th MOP, FDA's October 12, 2005 recommendations to EPA could not have taken this Decision into account. While two draft decisions were forwarded to the 17th MOP, neither decision was adopted in full by the MOP, and there is no way FDA could have known which decision would be adopted. Therefore, when FDA made its recommended allocation to EPA, it could not have taken Decision XVII/5 into account. One of the commenters stated that, under this Decision, EPA and FDA are required to factor in any final shipments of CFCs from the now-closed Weert CFC manufacturing plant.

EPA and FDA were aware of Decision XVII/5 at the time of publication of the proposal, and nothing in that decision required a change to the October 2005 FDA determination. Decision XVII/5(2) says: "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 operational supply is maintained by that manufacturer." This language is not in conflict with language in Decision XVI/12 from the previous year which states that Parties "should give due consideration to existing stocks \* \* \* of banked or recycled controlled substances as described in paragraph 1(b) of decision IV/25, with the objective of maintaining no more than one year's operational supply." FDA's determination did pre-date Decision

XVII/5, however, it is consistent with Decision XVII/5 as well as Decision XVI/12. Decision XVII/5 contains two details that Decision XVI/12 did not: It refers to stocks at the MDI manufacturing level and clarifies that both pre- and post-1996 stocks should be taken into account. FDA has informed EPA that in making their determination they took both pre-1996 and post-1996 stocks at the MDI manufacturing level into account. Even at the time Decision XVI/12 was taken, the U.S. Government articulated to Parties that the U.S. believed the terms on stocks in the Decision would be applied at the individual company level. The more recent Decision indicated other Parties' concurrence with this approach by specifically including the phrase "by that manufacturer." Thus, the decision taken in December 2005 did not have a substantive impact on FDA's determination made in October 2005.

Four commenters expressed the opinion that EPA did not adequately support its proposed essential use allocations for 2006 because EPA based the proposed 2006 allocations on outdated information. The commenters stated that FDA provided its determination to EPA on October 12, 2005, prior to several significant developments. Two of these commenters believe that EPA and FDA should take into account increases in HFA manufacturing, as well as the uptake of HFA products that began in January 2006 and that has increased from 3 percent to 10 percent of the overall albuterol market. One commenter stated that EPA and FDA should also consider the albuterol shortages that occurred in early 2006.

We understand concerns raised by the commenters that given the 2008 ban on the sale of albuterol CFC MDIs, the market may be rapidly shifting and a snapshot of data six to twelve months prior to an allocation may not represent actual essential needs. In response, EPA notes that the purpose of a comment period is to bring new information and opinions to the Agency's attention and that EPA does look at data that comes to us during the comment period.

While the Agency makes every reasonable effort to use best available data, it is also reasonable to create a process for data gathering and establish a cut off for new information. For example, it would be impossible for EPA to review and consider new data that comes to us the day a rule is signed.

Although there is an established process for gathering information, the Agency does make every reasonable effort to use newer data when feasible.

For example, EPA does evaluate new information that comes to the Agency during the comment period. In the April 11, 2006, proposed rule, the Agency stated “[t]he amounts listed in this proposal are subject to additional review by EPA and FDA if new information demonstrates that the proposed allocations are either too high or too low.”

On the specific matter of revising the allocations in this rule based on more recent stock data, the Agency has data on stock holdings as of the end of 2005 and mid-2006 which is more recent data than was available at the time of publication of the proposed rule. However, these data do not indicate that the October 2005 FDA determination should be revised. Information on individual stock holdings is in the confidential portion of the docket for this rulemaking.

One commenter stated that EPA based its proposed 2006 CFC essential use allocations on information on the number of MDI units produced during 2004 and anticipated to be produced during 2005, which was obtained from CFC MDI manufacturers via CAA section 114 letters. The commenter notes that actual 2005 information is now available both from companies themselves via section 114 requests and from public sources such as IMS data. The commenter also believes that FDA’s recommendations to EPA regarding the 2006 essential use allocations were based on outdated and insufficient information. The commenter notes that since FDA’s recommended allocation levels were sent to EPA in a letter dated October 12, 2005, FDA did not have complete 2005 production data at hand on which to base its conclusions. Further, any data that FDA used regarding stockpiles prior to the end of the calendar year would have been incomplete, since manufacturers replenished their CFC stockpiles from October through December 2005.

The commenter stated that EPA’s reliance on outdated data is not in line with the well-established administrative law principle that “an agency must examine relevant data” in making its determinations and that failure to do this “either is arbitrary decision making or at least prevents a court from finding it non-arbitrary.” With respect to EPA’s proposed 2006 allocations, according to the commenter, the most pertinent data are from 2005, and the use of 2004 data cannot be justified. Thus, based on administrative law standards, the commenter believes that EPA will have acted in an arbitrary and capricious fashion by not using more recent and relevant data. The commenter

recommends, therefore, that EPA send new Section 114 letters to manufacturers requesting current information and that FDA use this information to prepare a new determination of recommended allocations for 2006.

EPA uses a well-established rulemaking process which includes a timeline for collection of data, development of a proposed rule, consideration of comments, and issuance of a final rule. As stated above, EPA agrees that the Agency should use best available data but notes that a reasonable cut off for new information is required in any process. Therefore, best available data in this circumstance may be the information available as of the development of the proposal, as supplemented by public comments and information generated by regulatory reporting requirements in time for consideration during the development of the final rule. For the past ten years of the essential use program, the Agency has based proposed allocations largely on data obtained during the year prior to the allocation.

EPA does evaluate new information that comes to the Agency during the comment period and through periodic reports from regulated entities. New information on stock holdings and HFA MDI market penetration has been made available to EPA and FDA and the October 2005 FDA determination is still appropriate given this new information. The Agency further notes that it placed the 2005 accounting framework (which includes actual use data for 2005) in the public docket for this proposed rulemaking and relied on it in developing the rule.

In the October 2005 letter to EPA, FDA stated that its determination of the amount of CFCs necessary for production of essential MDIs is lower than the total amount requested by manufacturers, and in reaching this estimate, FDA took into account the manufacturers’ production of MDIs that used CFCs as a propellant in 2004, the manufacturers’ estimated production in 2005 and 2006, the manufacturers’ current stockpile levels, and the presence on the market of two albuterol MDIs that do not use CFCs. The letter also informed EPA that FDA based its determination for 2006 on an estimate of the quantity of MDIs using CFCs as a propellant that would be necessary for manufacturers to maintain a 12-month stockpile, consistent with paragraph 3 of Decision XVI/12.

In making allocations, government experts examine projected MDI manufacturing demand for the year in question. One important element in

arriving at an estimate of projected demand is to examine information on past demand and production. If EPA or FDA were to see use data in 2005 that was a significant departure from use in the preceding years, such data would be of interest to the agencies and could lead to a different conclusion. There was no 2005 data provided to the EPA that indicate a rapid change in the marketplace beyond the amounts offset by the IVAX production shortfall and therefore no need for FDA to revise its October 2005 determination.

One commenter noted that EPA proposed the amount recommended by FDA without revisions. This commenter urged EPA to revise FDA’s recommended allocations to take into account more recent stocks data in determining the 2006 allocations. In a similar context, the commenter also states that EPA and FDA did not apply the terms of Decision XVII/5 at the time of allocation. The commenter notes that Protocol decisions are part of Protocol law and are also U.S. law for purposes of essential use allocations.

The commenter’s paraphrase of CAA section 604(d)(2) reverses the EPA and FDA roles. The statute says that EPA “shall authorize,” to the extent consistent with the Montreal Protocol, if FDA, in consultation with EPA, determines such authorization to be necessary. Thus, FDA plays the primary role in the determination, although consultation must (and does) occur. Pursuant to the statutory language, EPA does evaluate whether the essential use allowances are consistent with the Montreal Protocol prior to issuing a proposed or final rule. The allowances contained in this final rule are fully consistent with the Protocol and Decisions of the Parties. In addition, as explained above, EPA concurs with FDA’s interpretation and application of the phrase “one-year operational supply” as used in Decision XVII/5. In regard to the legal status of decisions of the Parties, EPA refers readers to the recent DC Circuit opinion in *NRDC v. EPA*, D.C. Cir. No. 04–1438 (August 29, 2006), as well as to the discussion of the matter in EPA’s “Supplemental Brief for the Respondent,” filed in that same case. These documents are available in the docket for this action.

One commenter noted that neither FDA nor EPA has explained how they propose to define and implement the key terms in Decision XVII/5. According to the commenter, the lack of definitions in the proposed rulemaking is not only counter to EPA’s obligation to provide notice and opportunity for the public to comment, but also means that each company will apply its own definition.



The commenter asserted that EPA's failure to define terms in the proposed rule is not in line with well-established requirements for notice and comment under the Administrative Procedures Act. The commenter also stated that there is no record in the docket to support EPA's claim in the proposed rule that it has "confirmed with FDA that this determination is consistent with Decision XVII/5 \* \* \*" and that neither agency has provided any information on the methodology used to determine that the allocations were in conformity with the Decision.

In reaching its determination, FDA used the plain meaning of the phrase "one-year operational supply." A company's "one-year operational supply" is the amount needed to supply that company's manufacturing operations for one year. One commenter provided a helpful refinement of this concept by pointing out that its operations require a blend of CFCs -11, -12, and -114, and that the presence of only one or two of these compounds does not constitute an operational supply. This comment suggests that the use of the phrase in the proposed rule was sufficiently clear to put commenters on notice of FDA's interpretation. Because the Agency used the plain meaning of the words "one-year operational supply" there was no need to propose a definition for public comment.

One commenter urged EPA to consider making essential use allowance allocations earlier in the year in order to minimize the logistical challenges posed in manufacturing essential MDIs. Since CFC-114 is produced throughout the year, this commenter could make use of its allowances if they were awarded sooner. A second commenter noted that the domestic ruling on essential use allowances for 2006 has been delayed due to extended consideration in the Montreal Protocol negotiation. As a result, the commenter stated the opinion that it is essential that domestic implementation occur at the earliest date to allow for production planning and execution to meet this year's CFC MDI producer needs.

EPA makes every effort to allocate allowances in a timely manner but is affected by factors beyond its control, including the timing of Decisions and the length of the regulatory process itself. A final decision for 2006 allocations was only taken in December 2005.

#### *E. EPA May Not Allocate Allowances to Companies That Fail To Demonstrate Research and Development of Alternatives*

One commenter stated that EPA should not allocate essential use CFCs to companies that have not fully complied with Decision VIII/10 by clearly establishing that they are undertaking efforts to develop non-CFC alternatives. The commenter does not believe that Armstrong Pharmaceuticals' research and development program is adequate to achieve results by the December 31, 2008 phaseout deadline. To that end, the commenter recommends that EPA use its section 114 authority to investigate the resource commitment and level of effort of any research and development effort by Armstrong Pharmaceuticals. Unless EPA and FDA conclude that Armstrong's research and development program has a realistic chance of success by December 31, 2008, this commenter believes that Armstrong should be denied an essential use exemption in 2006 on this basis.

The Agency agrees that companies should undertake research efforts to demonstrate a commitment to eliminate the need for an exemption, but disagrees with the premise that such efforts must be completed by December 31, 2008. Finally, EPA refers readers to the extensive discussion on this matter in the 2005 final allocation rule (70 FR 49838-9) and to a 2002 **Federal Register** notice that addresses this topic (67 FR 6355).

#### *F. Transition to Non-CFC Metered Dose Inhalers*

Two commenters expressed concern that the allocations may have negative effects on the transition to non-CFC MDIs. One of these commenters recommended that EPA and FDA consider how CFC allocations at this end stage might affect transition at the patient level. According to this commenter, the proposed allocations for 2006 could result in a transition period as long as 30 months in which both CFC and HFA albuterol have a substantial market share. Both commenters stated that a mixed market of CFC and HFA MDIs could have negative health effects on patients. For example, physicians might not know which product their patients are using and patients also may be confused, which could result in adverse health outcomes (e.g., since HFA inhalers may feel different than the CFC one, patients may overuse the HFA device). Both commenters also believe that mixed signals from EPA and FDA about albuterol and new HFA

technology could cause confusion and uncertainty. As a result, one of the commenters believes there could be a backlash against the MDI transition, if not about ozone layer protection in general. In light of these factors, one commenter expressed the opinion that the 2006 allocations should send a message consistent with what has been occurring in the market place. Therefore, the commenter urged EPA and FDA to reevaluate the proposed allocation of 700 MT for CFC albuterol MDIs (including 147.7 MT allocated to one company, which according to the commenter is more than twice that company's one-year operational supply) so that those allocations do not impede the transition to non-CFC MDIs.

Another commenter stated that a near-term, achievable transition date in 2005 or early 2006 would have sent a strong message to manufacturers, the medical community, and patients, providing a catalyst for the planning needed to transition to non-CFC MDIs. In addition, given the albuterol shortages reported in early 2006, this commenter stated that the continued and expanded availability of HFA MDIs is critical to ensuring that additional shortages do not occur and that the transition is as seamless as possible for patients.

Both commenters urged EPA and FDA to use the allocation tool to promote a smooth transition during the end stage of the albuterol transition, in which HFA manufacturers are completing the scale-up of their production capacity. One commenter expressed the opinion that facilitating an orderly and transparent transition is consistent with EPA's authority and affirmative legal responsibility under the Clean Air Act to implement the Montreal Protocol. The commenters state that by limiting CFCs to only those uses that are necessary, EPA and FDA would enhance the likelihood of a smooth transition in several ways, which include sending a signal that the U.S. is serious about facilitating a transition away from CFC MDIs; reinforcing the idea that the transition offers positive opportunities for patients and physicians to improve medical outcomes; introducing further certainty about when HFA MDI supplies will be adequate; and preventing the market from sliding back into CFC albuterol, as this would engender confusion and risks to patient health.

FDA previously conducted an extensive regulatory process to determine when albuterol MDIs would no longer be considered essential uses, evaluating the factors raised by the commenters above. FDA concluded in that rulemaking that albuterol CFC MDIs



would no longer be essential at the end of 2008. As of 2006, however, CFC albuterol MDIs continue to appear on FDA's list of essential MDIs and FDA has determined that limited production of new CFCs is necessary to protect patient safety in 2006. Despite the continued need for CFC albuterol MDIs, EPA would note that the transition to

CFC-free albuterol MDIs is well underway and the number of HFA MDIs on the market today is evidence of that fact.

**III. Allocation of Essential Use Allowances for Calendar Year 2006**

With this action, EPA is allocating essential use allowances for calendar

year 2006 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 2006

Company	Chemical	2006 Quantity (metric tons)
<b>(i) Metered Dose Inhalers (for oral inhalation) for Treatment of Asthma and Chronic Obstructive Pulmonary Disease</b>		
Armstrong Pharmaceuticals .....	CFC-11 or CFC-12 or CFC-114 .....	147.50
Boehringer Ingelheim Pharmaceuticals .....	CFC-11 or CFC-12 or CFC-114 .....	116.50
Inyx (Aventis) .....	CFC-11 or CFC-12 or CFC-114 .....	106.40
Schering-Plough Corporation .....	CFC-11 or CFC-12 or CFC-114 .....	556.00
3M Pharmaceuticals .....	CFC-11 or CFC-12 or CFC-114 .....	0.00
Wyeth .....	CFC-11 or CFC-12 or CFC-114 .....	76.00

**IV. Statutory and Executive Order Reviews**

*A. Executive Order 12866: Regulatory Planning and Review*

Under Executive Order 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 Executive Order 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 82.8(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 in 40 CFR are listed in 40 CFR part 9.

*C. Regulatory Flexibility Act*

EPA has determined that it is not necessary to prepare a regulatory flexibility analysis in connection with today's final rule. EPA has also determined that this rule will not have a significant economic impact on a substantial number of small entities. For purposes of assessing the impact of today's final rule on small entities, small entities are defined as: (1) Pharmaceutical preparations manufacturing businesses (NAICS code 325412) that have less 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, EPA has concluded 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. Sections 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 this 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 phaseout 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 Executive Order 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5-501 of the Order has the potential to influence the regulation. This rule is not subject to Executive Order 13045 because it implements the phaseout schedule and exemptions established by Congress in Title VI of the Clean Air Act.

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

This rule is not subject to 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 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 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 October 4, 2006.

**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 October 4, 2006. 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, Reporting and recordkeeping requirements.

Dated: September 27, 2006.

**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 2006

Company	Chemical	2006 Quantity (metric tons)
<b>(i) Metered Dose Inhalers (for oral inhalation) for Treatment of Asthma and Chronic Obstructive Pulmonary Disease</b>		
Armstrong Pharmaceuticals .....	CFC–11 or CFC–12 or CFC–114 .....	147.50
Boehringer Ingelheim Pharmaceuticals .....	CFC–11 or CFC–12 or CFC–114 .....	116.50
Inyx (Aventis) .....	CFC–11 or CFC–12 or CFC–114 .....	106.4
Schering-Plough Corporation .....	CFC–11 or CFC–12 or CFC–114 .....	556.00
3M Pharmaceuticals .....	CFC–11 or CFC–12 or CFC–114 .....	0.0
Wyeth .....	CFC–11 or CFC–12 or CFC–114 .....	76.0

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[FR Doc. E6–16372 Filed 10–3–06; 8:45 am]  
BILLING CODE 6560–50–P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA–HQ–OPP–2006–0670; FRL–8092–7]

**Flumetsulam; Pesticide Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of flumetsulam in or on beans (dry). Dow AgroSciences LLC requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

**DATES:** This regulation is effective October 4, 2006. Objections and requests for hearings must be received on or before December 4, 2006, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2006–0670. All documents in the docket are listed in the index for the docket. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (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 in the electronic docket at

<http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

**FOR FURTHER INFORMATION CONTACT:** Phil Errico, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6663; e-mail address: [errico.philip@epa.gov](mailto:errico.philip@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural