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Protection of Stratospheric Ozone: Allocation of Essential Use Allowances for Calendar Year 2005; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[FRL–7958–2]

RIN 2060–AM50

Protection of Stratospheric Ozone: Allocation of Essential Use Allowances for Calendar Year 2005

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 2005. Essential use allowances enable a person to obtain controlled class I ODSs as an exemption to the regulatory ban of production and import of these chemicals, which became effective on January 1, 1996. EPA allocates essential use allowances for exempted production or import of a specific quantity of class I ODS solely for the designated essential purpose. The allocations total 1,820.48 metric tons of chlorofluorocarbons for use in metered dose inhalers.

DATES: This final rule is effective August 19, 2005.

ADDRESSES: Materials related to this rulemaking are contained in EPA Air Docket OAR–2004–0063. The EPA Air Docket is located at EPA West Building, Room B102, 1301 Constitution Avenue, NW., Washington, DC, 20460. The Air Docket is open from 8:30 a.m. until 4:30 p.m. Monday through Friday. Materials related to previous EPA actions on the essential use program are contained in EPA Air Docket No. A–93–39.

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I. General Information

How Can I Get Copies of Related Information?

1. Docket

EPA has established an official public docket for this action at Air Docket ID No. OAR–2004–0063. The official public docket consists of the documents specifically referenced in this action and other information related to this action. Hard copies of documents related to previous essential use allocation rulemakings and other actions may be found in EPA Air Docket ID No. A–93–39. The public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The public docket is available for viewing at the Air and Radiation Docket in the EPA Docket Center, (EPA/DC) EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center 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 Reading Room is (202) 566–1741, and the telephone number for the Air and Radiation Docket is (202) 566–1742. EPA may charge a reasonable fee for copying docket materials.

2. Electronic Access

An electronic version of the public docket is available through EPA's electronic public docket and comment system, ''EPA Dockets.'' You may use EPA Dockets at *http://www.epa.gov/edocket/* to view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket identification number.

II. Basis for Allocating Essential Use Allowances

A. What Are Essential Use Allowances?

Essential use allowances are allowances to produce or import certain ozone-depleting chemicals in the U.S. for purposes that have been deemed ''essential'' by the Parties to the Montreal Protocol and the U.S. Government.

The Montreal Protocol on Substances that Deplete the Ozone Layer (Protocol) is an international agreement aimed at reducing and eliminating the production and consumption [1] of stratospheric ozone depleting substances (ODSs). The elimination of production and consumption of class I ODSs is accomplished through adherence to phaseout schedules for specific class I ODSs,[2] including: 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 Protocol and the Clean Air Act (Act) provide exemptions that allow for the continued import and/or production of class I ODS for specific uses. Under the 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

[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.

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.''

B. Under What Authority Does EPA Allocate Essential Use Allowances?

Title VI of the Act implements the 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 phase out 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 diseases.

(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 Protocol, under Decision XV/8, additionally allows 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 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 will allocate essential use allowances, the Parties to the Protocol must first approve 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 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 today's action were first nominated by the United States in January 2003.

Once the U.S. nomination is approved by the Parties, 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 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 2005, the Parties authorized the United States to allocate up to 1,902 metric tons of CFCs for essential uses.

EPA published a proposed rule on December 22, 2004 (69 FR 76655) that would have allocated a total of 1,524.58 metric tons of allowances. EPA subsequently determined that the amount proposed to be allocated to one company, Armstrong Pharmaceuticals, was incorrect. Specifically, EPA had proposed to allocate to Armstrong 29 metric tons, but the amount should have been 270.90 metric tons. EPA published a supplemental proposal on February 23, 2005 (70 FR 8753) to correct the error, which increased the total amount of proposed allowances to 1,766.48 metric tons. Today's rule finalizes both the proposed rule and the supplemental proposed rule.

III. Response to Comments

EPA received eight sets of comments from six individual commenters on the proposed rule and the supplemental proposed rule, four of which were late comments. One commenter objected to the granting of essential use status generally. One commenter requested additional allowances for 2005. The other four commenters presented arguments related to the obligations of the United States under the Montreal Protocol and the requirements of the Clean Air Act with respect to the proposed allocations. The comments are addressed in more detail below.

A. EPA Should Not Allocate Essential Use Allowances Generally

One commenter opposed exempting Class I substances for any purpose, including asthma medication, because non-ozone depleting alternatives have been developed (OAR–2004–0063–0006). EPA disagrees with this comment. Section 604 of the Act directs

EPA to authorize production of CFCs for essential MDIs if FDA, in consultation with EPA, determines such production to be necessary. FDA has found the use of ozone-depleting substances to be essential in certain metered dose inhalers for the treatment of asthma and chronic pulmonary disease (see 21 CFR 2.125(e)). As established by final rule on July 24, 2002 (67 FR 48370), FDA will determine through rulemaking when an MDI is no longer essential due to the availability of safe and effective alternatives.

The same commenter also stated, ''[A]ll of the information these polluting companies submit should be open to the public.'' The information submitted was claimed as confidential. That information is being treated in accordance with EPA's regulations on confidential business information at 40 CFR 2.201 through 2.311.

B. EPA Should Not Allocate Essential Use Allowances for Production of Albuterol MDIs

One commenter wrote that EPA should not allocate essential use allowances for use in CFC albuterol MDIs because they are ''non-essential'' and the allocations would be ''inconsistent with Decisions of the Parties to the Montreal Protocol'' (OAR–2004–0063–0012). The commenter referenced a letter sent by the Natural Resources Defense Council (NRDC) to EPA on May 13, 2004, that addressed the inclusion of CFCs for albuterol MDIs in the United States' 2006 essential use nomination. EPA responded with a letter dated July 12, 2004, in which we said, ''Until FDA issues a final rule to delist albuterol MDIs (with an identified effective date) in accordance with its own regulations and the Administrative Procedures Act, it is premature and contrary to law for EPA unilaterally to conclude that CFC albuterol MDIs are in fact no longer essential in the United States and to remove this essential use from the U.S. nomination for 2006.'' These letters have been placed in EPA Docket no. OAR–2004–0063. FDA since announced its decision that CFC albuterol MDIs will no longer be essential after December 31, 2008 (70 FR 17168, April 4, 2005). Thus, FDA continues to regard CFC albuterol MDIs as essential for the current control period. EPA is therefore allocating essential use allowances for CFC albuterol MDIs in this final rule.

C. Aventis Pharmaceuticals Requested Additional CFCs for 2005

Aventis Pharmaceuticals submitted to the docket a request for additional allowances in the amount of 60 metric tons, which if allocated would bring the company's total allocation for 2005 to 117 metric tons. A portion of the additional CFCs would be used for products exported outside the United States. EPA and FDA considered this request and determined to grant additional allowances for MDI products marketed in the United States; the relevant correspondence has been placed in EPA Docket no. OAR–2004–0063.

EPA is not granting additional allowances to Aventis for production of CFC MDIs that would be sold outside the United States. Under section 604(d)(2) of the Act, EPA authorizes production of class I substances ''if such authorization is determined by the Commissioner in consultation with the Administrator, to be necessary for use in medical devices.'' EPA and FDA have concluded that they currently lack sufficient information about whether the MDIs in question have been declared essential in those counties by their public health authority, whether they could otherwise be considered essential, or whether production of CFCs for these MDIs is necessary. FDA is thus unable to render a determination on those issues. Without such determinations, EPA is not allocating allowances for those MDIs.

Following publication of the proposed rule in the **Federal Register** and the request by Aventis for increased allowances, EPA was notified that Aventis sold certain of its assets related to MDI production to Inyx USA. Therefore, today's action assigns the allowances proposed for Aventis, including the additional allowances, to Inyx.

EPA received separate but similar sets of comments from the International Pharmaceutical Aerosol Consortium (IPAC), NRDC, the U.S. Stakeholders Group on MDI Transition, and GlaxoSmithKline (GSK), a pharmaceutical company and member of IPAC. EPA's responses to these comments are grouped below in accordance with the major points made by the commenters. In many instances EPA references the GSK comments because they were both representative of and more detailed than other comments.

D. Effect of Montreal Protocol Decisions

GSK commented that ''EPA's statutory obligation to fully implement the provisions of the Montreal Protocol includes decisions by the Parties to the Protocol'' (OAR–2004–0063–0008, p. 2). EPA previously discussed the relevance of Decisions of the Parties 69 FR 76984–76985. Today's action is fully consistent with the Montreal Protocol and the Decisions of the Parties bolster, rather than detract from, EPA's interpretation and application of the Protocol's essential use provisions.

E. EPA Must Reevaluate FDA's Determinations Regarding Essential Use Allowance Volumes

GSK argued that EPA must adhere to Montreal Protocol Decisions and commented, ''The fact that FDA has recommended [certain allocation] levels does not absolve EPA from evaluating consistency with Protocol decisions at the time it makes * * * allocations'' (OAR–2004–0063–0008, p. 3). GSK also argued that EPA may not rely on the levels authorized by the Parties to the Protocol, but must reapply relevant Decisions in its rulemaking process to ensure consistency with the Protocol.

EPA understands today's rulemaking to be fully consistent with the relevant Protocol Decisions and with its obligations under the Protocol and Federal law. As explained elsewhere in this section of the preamble, most of the Decisions cited by GSK specifically reference the nomination process, not the allocation process. EPA accordingly reviews those Decisions in preparing the nomination.

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

GSK argued that Decisions VIII/10, XV/5, and IV/25 require EPA to deny allowances to companies that did not submit research and development information. GSK stated that it is ''highly likely'' that not all companies that requested allowances have submitted such information, and suggested that the U.S. nomination may have been non-responsive on this point (OAR–2004–0063–0008, p. 8).

EPA disagrees with the commenter's interpretation of Decision VIII/10 and its effort to establish links between this Decision and others. Decision VIII/10 provides that Parties ''will request companies applying for MDI essential-use exemptions to demonstrate ongoing research and development of alternatives to CFC MDIs with all due diligence'' as well as to report in confidence on resources and progress in alternatives development. In accordance with this Decision, since 1997 EPA has requested applicants to provide this information when submitting requests for CFC essential use nominations. (67 FR 66148, October 30, 2002). Thus, EPA's interpretation is consistent with this Decision.

Contrary to GSK's suggestion, Decision VIII/10 does not require any

action to be taken at the allocation stage. Instead, it states only that Parties ''will request'' information on research and development from companies. In addition, Decision VIII/10 does not state how to use the information. It does not require the United States to report to the Parties on research and development, either in connection with essential use nominations or otherwise. Nor does it serve as a basis for denying an essential use allowance request. See, for example, 67 FR 6355, February 11, 2002.

GSK commented that EPA should not allocate allowances to companies that do not plan to replace their CFC MDI product with a non-CFC alternative and are not conducting research to develop new products (OAR–2004–0063–0008, p. 9). Decision VIII/10, however, does not say that all applicants must demonstrate ongoing research and development, regardless of the circumstances. EPA interprets the Parties' intent in taking Decision VIII/10 to be, as stated on its face, ''to promote industry's participation on a smooth and efficient transition away from CFC based MDIs'' generally. Granting allowances for a CFC MDI product, if the product is listed as essential and production of CFCs is determined by the Commissioner of FDA to be necessary under section 604(d)(2) of the Act, allows industry and patients to continue to make and use needed products while non-CFC alternatives are developed. This is consistent with the Decision VIII/10 standard of ''due diligence.''

Companies may elect to drop their CFC products and withdraw from the essential use program over time in accordance with their business plans. EPA has seen at least two instances in which companies—Sciarra Laboratories and PLIVA—withdrew from the essential use program (by no longer requesting essential use allowances) without ultimately reformulating their products in a non-CFC version, leaving the need for their products to be filled by other essential MDIs or alternatives. This process is consistent with the goal of promoting a ''smooth and efficient transition.'' EPA has placed in Docket no. OAR–2004–0063 **Federal Register** notices from 2001 and 2002 indicating Sciarra's withdrawal from the program, as well as the **Federal Register** notice from 2004 indicating the last year in which PLIVA received allowances (PLIVA is not included in today's rule). Additionally, EPA has docketed the U.S. response to Decision XIV/5, sent to the Ozone Secretariat on February 23, 2005, in which the U.S. identified all CFC and non-CFC inhalers sold domestically.

GSK stated that ''it is not reasonable to conclude that because a parent company has presented information to demonstrate its compliance with Decision VIII/10, that such compliance automatically applies to that company's subsidiaries. * * * EPA has not provided any information by which the public can reasonably conclude that Schering-Plough has shared the fruits of [its] collaboration with its subsidiary, Warrick Pharmaceuticals'' (OAR–2004–0063–0008, p. 11). GSK also stated that EPA must deny allocations to Schering for Warrick's product based on Schering's alleged failure to submit information on Warrick's research and development efforts. However, as noted above, Decision VIII/10 calls for countries to request information from companies regarding research and development, and does not speak to the issue of denying petitions. Furthermore, the decision does not indicate whether the Parties had any specific intent regarding parent-subsidiary collaborations. Given the underlying purpose of the Decision to encourage research and development by the industry as a whole and the lack of formal corporate distinctions in the Protocol, EPA disagrees with GSK's construction.

GSK also incorrectly concludes that Decision XV/5 establishes that ''EPA * * * allocations must be assessed for each active ingredient and each intended market'' (OAR–2004–0063–0008, p. 10). In Decision XV/5, the Parties agreed: ''To request that Parties * * * when submitting their nominations for essential-use exemptions for CFCs for metered-dose inhalers, specify, for each nominated use, the active ingredients, the intended market for sale or distribution and the quantity of CFCs required.'' Decision XV/5(2). This Decision refers specifically to the nomination process. It does not address research and development reporting, nor does it affect EPA's authority with regard to the granting of essential use allowances on that ground.

Finally, GSK's citation of Decision IV/25 is also inapposite. GSK stated that if a company's efforts to research and develop alternatives, to collaborate with others, and to share such information with its subsidiaries are ''insufficient,'' then it has not taken ''all economically feasible steps * * * to minimize the essential use'' in accordance with Decision IV/25(1)(b)(i) (OAR–2004–0063–0008, pp. 10–11). EPA disagrees with the commenter's suggestion of a direct relationship between Decisions IV/25 and VIII/10. Decision VIII/10 does not make reference to Decision IV/25. Also, GSK's proposed construction is unreasonable due to the practical difficulties associated with determining whether an individual company's research and development efforts constitute ''all economically feasible steps'' for that company. Such a determination could require detailed knowledge of the company's financial status and business plans, as well as an understanding of the economic importance of the company's MDI products relative to other products manufactured by the company.

Moreover, Paragraph 1(b)(i) of Decision IV/25 speaks to minimization of particular essential uses, not to general research and development. EPA has received information from applicants regarding their efforts to minimize the essential use and associated emissions. The United States reports to the Parties on these efforts in the annual essential use nomination. The essential use nomination for 2005 (pp. 12–13), for example, listed several waste minimization strategies employed in the manufacture of MDIs (see Docket OAR–2004–0063). Information submitted by individual companies in connection with annual essential use nominations has been claimed as confidential and is being treated in accordance with EPA's regulations on confidential business information a 40 CFR 2.201 through 2.311.

G. EPA Must Reduce Allocations of Essential Use Allowances by the Amount That CFC Stockpiles Exceed a One-Year Supply

Commenters argued that because Decision XVI/12 states that countries should pursue ''the objective of maintaining no more than one year's operational supply [of CFCs],'' and because Decision IV/25 states that production and consumption should be permitted only if ''the controlled substance is not available in sufficient quantity and quality from existing stocks,'' that EPA must reduce allocations if stockpiles of CFCs amount to more than a one-year supply. GSK also argued that section 604(d)(2) of the Clean Air Act reinforces this requirement by allowing the Administrator to authorize new production of class I substances for medical devices only if ''such action is consistent with the Montreal Protocol'' (OAR–2004–0063–0008, p. 13).

EPA believes that this argument misreads the Decisions in question and that today's action is fully consistent with those Decisions and the Protocol. At the last Meeting of the Parties in November 2004, the Parties specifically negotiated and addressed in text the issue of stockpiles for CFC MDIs. They concluded in Decision XVI/12 that

''Parties, when preparing essential use nominations for CFCs, should give due consideration to existing stocks * * * with the objective of maintaining no more than one year's operational supply.'' First, by its very terms, the Decision only applies prospectively, when countries make a nomination, not during any later domestic allocation process.

Second, Decision XVI/12 did not exist at the time of the 2005 U.S. nomination. The first nomination subject to Decision XVI/12, which the United States delivered to the Parties on February 2, 2005, stated, ''The USEPA monitors reserves through information provided by companies that receive essential use allowances. In putting forward our 2007 essential use exemption nomination, the United States carefully reviewed the size of company reserves, bearing in mind that information on reserves at the end of 2003 or 2004 is not a reliable indicator of the amounts that will be held, and their distribution at the beginning of 2007. Bearing in mind this uncertainty, the United States has given due consideration to the existence of stocks in accordance with Decision XVI/12'' (p. 16). Thus, the United States has acted in conformance with Decision XVI/12.

Third, Decision XVI/12 only sets an objective of a one-year operational supply. It does not establish an absolute limitation. Giving ''due consideration'' to the level of stocks at the time of nomination does not necessarily equate to adjusting the U.S. nomination if the stockpile data at that point in time indicate a supply greater than one year's worth. The commenters cited data regarding on-hand CFC supplies at the beginning of 2004. To the extent the commenters' concern is based on this data, EPA directs their attention to the more recent report filed with the Ozone Secretariat on February 23, 2005 (see Docket No. OAR–2004–0063).

GSK noted that Decision XVI/2 expressly references Decision IV/25. However, Decision IV/25 does not alter the plain meaning of Decision XVI/12, and indeed it could not, having been decided by the Parties twelve years before they decided Decision XVI/12. GSK also stated that Decision IV/25 independently requires EPA to reduce allocations to the extent that stockpiles are ''excessive.'' This statement assumes that the Decision's language could only apply to individual Parties, ignores its hortatory nature, and overlooks the fact that the Parties specifically chose, in Decision XVI/12, to address the stockpile topic by setting an ''objective'' and by referring to the nomination, not to any domestic allocation process.

GSK also referred to Decision XV/5(2), in which the Parties decided, among other things, ''[t]o request that Parties * * * when submitting their nominations for essential-use exemptions for CFCs for metered-dose inhalers, specify, for each nominated use, the active ingredients * * * and the quantity of CFCs required.'' GSK stated that the combined effect of Decisions IV/25 and XV/5 is that EPA must, ''[i]n most cases * * * assess stockpiles on a company-specific basis'' (OAR–2004–0063–0008, p. 13). As a consequence, GSK argued, EPA must consider both available stockpiles in the aggregate and as held by individual companies. If a single company holds stockpiles greater than one year's operational supply, then according to the commenter EPA must reduce the amount of that company's allocation.

GSK has incorrectly interpreted a Decision that explicitly refers to individual Parties' nominations as referring to individual Parties' licensing processes. The United States acted in accordance with Decision XV/5, which was taken in November 2003, by submitting the requested information in a letter to the TEAP co-chairs (dated April 21, 2004) in connection with the 2006 essential use nomination. The United States also sent updated information to the TEAP co-chairs on February 23, 2005, in connection with the 2007 essential use nomination. Decision XV/5, whether considered alone or together with Decision IV/25, does not require the United States to take any action other than to submit the requested information as part of its essential use nomination. GSK did not explain the assertion that the two Decisions, taken together, provide more direction than either provides on its face, nor is there any indication of a direct relationship between the two Decisions. Decision XV/5 does not make reference to Decision IV/25. Furthermore, the U.S. nomination for 2005 had already been submitted at the time the Parties took Decision XV/5 and thus Decision XV/5 did not apply to that nomination because it post-dated it.

Another commenter quoted the May 2004 TEAP Report (see Docket no. OAR–2004–0063) to the effect that ''individual companies may hold a substantial and, perhaps, disproportionate amount'' of a Party's stockpile (OAR–2004–0063–0011, p. 2). EPA does not agree with this commenter that the statements in the TEAP report—a document that has never been formally adopted by the United States—regarding individual holdings mean that Decision XVI/12 must or should be read as relating to individual holdings. The TEAP only serves as an advisory body to the Parties to inform their decision making. It is not a directive body. Moreover, the natural reading of Decision XVI/12 is that each Party's objective should be to maintain no more than one year's (aggregate) supply. Paragraph 3 of that Decision states that ''Parties * * * should give due consideration to existing stocks * * * with the objective of maintaining no more than one year's operational supply.'' The ''Parties'' are the subject of the sentence and are thus the entities to which the phrase ''objective of maintaining no more than one year's operational supply'' pertains.

H. EPA Must Comply With the Act's Requirements for Notice and Comment Rulemaking

GSK stated that EPA, in our supplemental proposal to correct Armstrong's allocation, failed to comply with section 307(d) of the Act. Section 307(d)(3) directs EPA to make available, among other items, the factual data on which a proposed rule is based and the methodology used in obtaining and analyzing those data. GSK stated that the supplemental proposal was based on information that had not been placed in the docket, and also that the supplemental proposal was not justified based on information that EPA had made public. GSK also stated, ''Even if it were correct that a requesting company has sufficient information to comment on its own proposed allocation, neither EPA nor FDA have [sic] provided any basis for a different interested party to meaningfully comment on that allocation'' (OAR–2004–0063–0016, p. 3).

As stated above, the information on which FDA, in consultation with EPA, based the proposed allocations was claimed confidential by the submitting companies, including Armstrong Pharmaceuticals. As a consequence, EPA has treated this information in accordance with our regulations on confidential business information at 40 CFR 2.201 through 2.311. EPA has entered placeholder documents in the public portion of the docket to indicate the documents that we placed in the confidential portion.

With respect to the methodology used to determine the proposed allocations, EPA described the process for allocating essential use allowances in the preamble to the proposed rule published on December 22, 2004 (69 FR 76657). Section 604(d)(2) of the Act directs the Agency to authorize production of class I substances ''if such authorization is determined by the Commissioner, in consultation with the

Administrator, to be necessary for use in medical devices.'' EPA entered the Acting Commissioner's letter of determination (OAR–2004–0063–0005), as well as the FDA's subsequent letter of correction (OAR–2004–0063–0010), into the public docket for comment. EPA also explained in the preamble of the supplemental proposal that the allocation originally proposed for Armstrong Pharmaceuticals was based on an error, and the purpose of the supplemental notice was to correct the error. Portions of the correspondence regarding the nature of the error have been placed in the confidential portion of the docket due to concerns regarding disclosure of information claimed as confidential. A placeholder has been entered in the public portion of the docket with respect to this information.

EPA thus has made public the most information possible given our obligations regarding the treatment of information claimed as confidential. Therefore, EPA has acted in accordance with section 307(d) of the Act with respect to making public the basis and methodology for our proposed allocations. EPA has also acted in accordance with section 604(d)(2) of the Act. EPA does not have discretion to refuse to authorize production that is consistent with the Montreal Protocol and that has been determined to be necessary by FDA in consultation with EPA.

I. The Increase in Armstrong's Proposed Allocation Was Not Supported by Publicly Available Information

GSK stated that the corrected allocation proposed for Armstrong Pharmaceuticals in the supplemental notice was too high and ''cannot be supported under the CAA or the Montreal Protocol'' (OAR–2004–0063–0016, p. 6). This commenter argued that Armstrong's actual MDI production in recent years, according to publicly available data, was far less than would warrant the amount of CFC production allowances that Armstrong would receive according to the supplemental proposed rule. Also, GSK stated that Armstrong ''must be holding huge stockpiles of CFCs—at least sufficient to supply its production for more than a year,'' and that by allocating additional allowances to Armstrong in 2005 EPA would violate the terms of the Montreal Protocol (OAR–2004–0063–0016, p. 5).

Because Armstrong has claimed its 2005 essential use allowance documentation as confidential, EPA is unable to respond to the points made by the commenter specifically with regard to Armstrong's proposed allocation. However, GSK made several assumptions that EPA may respond to in general terms. First, GSK assumed that a company uses all of the allowances it is allocated in a given year. This is not the case, as evidenced by the U.S. Accounting Framework, which since 2001 has shown that the amount authorized has consistently exceeded the amount actually acquired (Accounting Frameworks for 2001–2004 have been placed in Docket no. OAR–2004–0063). In the 2004 Accounting Framework, for example, the United States reported 964 metric tons of CFCs authorized but not acquired. This fact reflects an important aspect of the essential use program: Both the U.S. nomination and the subsequent allocation rule issued for a given year involve projections, and there is unavoidably some uncertainty associated with projections of demand for CFC MDIs. In the interest of ensuring public access to essential MDIs, EPA believes it is safer for public health to risk allocating more allowances than may be used than to allocate too few and risk a shortage.

Second, GSK assumed that a company would be able to generate a large stockpile of essential use CFCs by using all of its allowances to produce or import CFCs without actually using those CFCs to manufacture MDIs during the same control period. However, a company engaging in this practice would reveal itself in its reporting to EPA in accordance with regulations at 40 CFR 82.13(u). EPA's examination of the data from this reporting has led it to conclude that stocks are on a downward trend in recent years. EPA expects companies to manage their allowances in good faith consistent with the goals of the essential use program.

The proposition that any company has accrued stores of essential use CFCs many times in excess of its annual usage is contradicted by the Accounting Framework. Since 2001, the amount of CFCs that the United States reported to the Ozone Secretariat as on-hand at the end of the year (Column L of the Accounting Framework) has decreased every year, from 1,910 metric tons in 2001 to 1,521 metric tons in 2004. Excessive stockpiling of CFCs by one or more companies would be reflected in the Accounting Framework as an increase in on-hand CFCs.

Third, the commenter assumed that a company's allocations must be based on the company's prior record of production. If a company's projected need for CFCs is higher than past usage, the commenter suggests, then EPA should not authorize additional CFCs. It is true that a company's prior usage of CFCs is relevant to EPA's proposed allocations, which is why EPA's February 24, 2004, letter to MDI manufacturers required them to include in their essential use applications prior-year production data (OAR–2004–0063–0002). Nevertheless, past production alone is an insufficient basis for allocating allowances in light of the fact that market conditions may change, and a company may increase or decrease its levels of production accordingly. Thus, EPA's February 24, 2004, letter also requested information regarding anticipated needs during 2005. For this reason and the other reasons explained above, EPA disagrees with the conclusions reached by the commenter with regard to the proposed allocation for Armstrong.

IV. Allocation of Essential Use Allowances for Calendar Year 2005

With today's action, EPA is allocating essential use allowances for calendar year 2005 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 I.—ESSENTIAL USE ALLOCATION FOR CALENDAR YEAR 2005

Company	Chemical	Quantity (metric tons)
Metered Dose Inhalers (for Oral Inhalation) for Treatment of Asthma and Chronic Obstructive Pulmonary Disease		
Armstrong Pharmaceuticals	CFC–11 or CFC–12 or CFC–114	270.90
Boehringer Ingelheim Pharmaceuticals	CFC–11 or CFC–12 or CFC–114	480
Inyx USA, Ltd.[3]	CFC–11 or CFC–12 or CFC–114	111
Schering-Plough Corporation	CFC–11 or CFC–12 or CFC–114	816
3M Pharmaceuticals	CFC–11 or CFC–12 or CFC–114	69.18

TABLE I.—ESSENTIAL USE ALLOCATION FOR CALENDAR YEAR 2005—Continued

Company	Chemical	Quantity (metric tons)
Wyeth Pharmaceuticals	CFC–11 or CFC–12 or CFC–114	73.40

V. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

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

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

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

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

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that this regulatory action is a ''significant regulatory action'' because it raises novel legal or policy issues. As such, this action was submitted to OMB for Executive Order 12866 review. Changes made in response to OMB suggestions or recommendations will be documented in the public record.

Under section 6(a)(3)(B)(ii) of Executive Order 12866, the Agency must provide to OMB's Office of Information and Regulatory Affairs an ''assessment of the potential costs and benefits of the regulatory action, including an explanation of the manner in which the regulatory action is consistent with a statutory mandate and, to the extent permitted by law, promotes the President's priorities and avoids undue interference with State, local, and tribal governments in the exercise of their governmental functions.''

EPA is undertaking today's final action under the mandate established by section 604(d) of the Clean Air Act Amendments of 1990, which directs the Administrator to authorize the production of limited quantities of class I substances solely for use in medical devices, if the Commissioner of FDA determines that the authorization is necessary. The final allocations in today's rule are the amounts determined by FDA to be necessary for calendar year 2005.

EPA has not assessed the costs and benefits specific to today's final action. The Agency examined the costs and benefits associated with a related regulation. The Agency's Regulatory Impact Analysis (RIA) for the entire Title VI phaseout program 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 (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).

B. Paperwork Reduction Act

This action does not add any information collection requirements or increase burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et. seq.* OMB previously approved the information collection requirements contained in the final rule promulgated on May 10, 1995, and assigned OMB control number 2060–0170 (EPA ICR No. 1432.21).

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 instruction; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR Chapter 1.

C. Regulatory Flexibility Act

EPA has determined that it is not necessary to prepare a regulatory flexibility analysis in connection with this final rule. EPA has also determined that this rule will not have a significant economic impact on a substantial number of small entities. 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 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. 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

[3] As explained in section III.C of the preamble, allowances allocated to Aventis in the proposed rule are being allocated to Inyx in today's final rule.

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 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 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 August 19, 2005.

VI. Judicial Review

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

VII. 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 August 19, 2005. 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

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

Dated: August 17, 2005.

Stephen L. Johnson,

Administrator.

n 40 CFR part 82 is amended as follows:

PART 82—PROTECTION OF STRATOSPHERIC OZONE

n 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

n 2. Section 82.8 is amended by revising the table in paragraph (a) to read as follows:

§ 82.8 Grant of essential use and critical use allowances.

(a) * * *

TABLE I.—ESSENTIAL USE ALLOCATION FOR CALENDAR YEAR 2005

Company	Chemical	Quantity (metric tons)
Metered Dose Inhalers (for Oral Inhalation) for Treatment of Asthma and Chronic Obstructive Pulmonary Disease		
Armstrong Pharmaceuticals	CFC–11 or CFC–12 or CFC–114	270.90
Boehringer Ingelheim Pharmaceuticals	CFC–11 or CFC–12 or CFC–114	480
Inyx USA, Ltd	CFC–11 or CFC–12 or CFC–114	111
Schering-Plough Corporation	CFC–11 or CFC–12 or CFC–114	816
3M Pharmaceuticals	CFC–11 or CFC–12 or CFC–114	69.18
Wyeth Pharmaceuticals	CFC–11 or CFC–12 or CFC–114	73.40

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