implications.'' This proposed rule does not have tribal implications, as specified in Executive Order 13175. The EPA consulted with tribal officials early in the process of developing the October 17, 2006, rule to permit them to have meaningful and timely input into its development. Although tribal governments may elect to conduct ambient air monitoring, none of the proposed changes in today's rule apply directly to tribal governments. Thus, Executive Order 13175 does not apply to this rule.

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

Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62FR19885, April 23, 1997) applies to any rule that: (1) Is determined to be ''economically significant'' as defined under EO 12866, and (2) concerns an environmental health or 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 EO 13045 as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the EO has the potential to influence the regulation. This proposed rule is not subject to EO 13045 because it does not establish an environmental standard intended to mitigate health or safety risks.

H. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this proposed rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. The rule merely proposed to amend the October 17, 2006, final monitoring rule (71 FR 61236) by correcting printing errors, providing clarifications, and providing some new flexibility for PM_{10} monitoring on a case-by-case basis.

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

This proposed rule is not a ''significant energy action'' as defined in Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use'' (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. No significant change in the use of energy is expected because the total number of monitors for ambient air quality measurements will not increase above present levels. Further, we have concluded that this rule is not likely to have any adverse energy effects.

J. National Technology Transfer Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Public Law No. 104–113, 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This action does not involve technical standards, other than to make corrections and clarifications. Therefore, EPA did not consider the use of any voluntary consensus standards.

List of Subjects in 40 CFR Parts 53 and 58

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: April 30, 2007.

Stephen L. Johnson,

Administrator.

[FR Doc. 07–2237 Filed 6–11–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[EPA–HQ–OAR–2007–0297; FRL–8325–7]

RIN A2060–AO44

Protection of Stratospheric Ozone: Allocation of Essential Use Allowances for Calendar Year 2008

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to allocate essential use allowances for import and production of Class I ozone-depleting substances (ODSs) for calendar year 2008. Essential use allowances enable a person to obtain controlled Class I ODSs as part of an exemption to the regulatory ban on the production and import of these chemicals, which became effective as of January 1, 1996. EPA allocates essential use allowances for exempted production or import of a specific quantity of Class I substances solely for the designated essential purpose. The proposed allocations total 27.0 metric tons (MT) of chlorofluorocarbons (CFCs) for use in metered dose inhalers (MDIs) for 2008.

DATES: Written comments on this proposed rule must be received by the EPA Docket on or before July 12, 2007, unless a public hearing is requested. Comments must then be received on or before 30 days following the public hearing. Any party requesting a public hearing must notify the contact listed below under **FOR FURTHER INFORMATION CONTACT** by 5 p.m. Eastern Standard Time on June 18, 2007. If a hearing is held, it will take place on June 27, 2007 at EPA headquarters in Washington DC. EPA will post a notice on our Web site (*http://www.epa.gov/ozone*) announcing further information on the hearing if it is requested.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2007–0297, by one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.
- E-mail: *A-and-R-docket@epa.gov*.
- Fax: 202–566–9744.
- Mail: Air Docket, Environmental Protection Agency, Mailcode 2822T,

1200 Pennsylvania Ave., NW., Washington, DC 20460.

• Hand Delivery or Courier. Deliver your comments to: EPA Air Docket, EPA West 1301 Constitution Avenue, NW., Room 3334, Mail Code 2822T, Washington, DC 20460. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OAR–2007–0297. EPA's policy is that all comments received by the docket will be included in the public docket without change and may be made available online at *www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information through *www.regulations.gov* or e-mail that you consider to be CBI or otherwise protected. If you would like the Agency to consider comments that include CBI, EPA recommends that you submit the comments to the docket that exclude the CBI portion but that you provide a complete version of your comments, including the CBI, to the person listed under **ADDRESSES** above. The *www.regulations.gov* website is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *www.regulations.gov* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm*.

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Air Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. This Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Air Docket is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Kirsten M. Cappel, by regular mail: U.S. Environmental Protection Agency, Stratospheric Protection Division (6205J), 1200 Pennsylvania Avenue, NW., Washington, DC, 20460; by courier service or overnight express: 1301 L Street, NW., Room 1047C, Washington DC, 20005; by telephone: (202) 343–9556; or by e-mail: *cappel.kirsten@epa.gov*.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. General Information

What should I consider when preparing my comments?

1. *Confidential Business Information.* Do not submit this information to EPA through *www.regulations.gov* or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

• Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).

• Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

• Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

• Describe any assumptions and provide any technical information and/or data that you used.

• If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

• Provide specific examples to illustrate your concerns, and suggest alternatives.

• Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

• Make sure to submit your comments by the comment period deadline identified.

II. Basis for Allocating Essential Use Allowances

A. What are essential use allowances?

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

The Montreal Protocol is the international agreement aimed at reducing and eliminating the production and consumption [1] of ODSs. The elimination of production and consumption of Class I ODSs is accomplished through adherence to

[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).

phaseout schedules for specific Class I ODSs,[2] which include CFCs, halons, carbon tetrachloride, and methyl chloroform. As of January 1, 1996, production and import of most Class I ODSs were phased out in developed countries, including the United States.

However, the Montreal Protocol and the Clean Air Act (the Act) provide exemptions that allow for the continued import and/or production of Class I ODSs for specific uses. Under the Montreal Protocol, exemptions may be granted for uses that are determined by the Parties to be ''essential.'' Decision IV/25, taken by the Parties to the Protocol in 1992, established criteria for determining whether a specific use should be approved as essential, and set forth the international process for making determinations of essentiality. The criteria for an essential use, as set forth in paragraph 1 of Decision IV/25, are the following:

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

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

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

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

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

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

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

Title VI of the Act implements the Montreal Protocol for the United States.[3] 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 section 604(d)(1) of the Act, this exemption was available only until January 1, 2005. Prior to that date, EPA issued methyl chloroform allowances to the U.S. Space Shuttle and Titan Rocket programs.

(2) Medical devices (as defined in section 601(8) of the Act), ''if such authorization is determined by the Commissioner [of the Food and Drug Administration], in consultation with the Administrator [of EPA] to be necessary for use in medical devices.'' EPA issues allowances to manufacturers of MDIs that 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 alternatives are available or because existing quantities of this substance are large enough to provide for any needs for which alternatives have not yet been developed.

An additional essential use exemption under the Montreal Protocol, as agreed in Decision X/19, is the general exemption for laboratory and analytical uses. 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 exemption 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). In a December 29, 2005 final rule, EPA extended the general exemption for laboratory and analytical uses through December 31, 2007 (70 FR 77048), in accordance with Decision XV/8 of the Parties to the Protocol. EPA plans to update this exemption in accordance with future Decisions from the Parties and its own regulations.

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 Parties. The Parties make the final decisions on whether to approve a Party's essential use nomination at their annual meeting. This nomination process occurs approximately two years before the year in which the allowances would be in effect. The allowances proposed for allocation for 2008 were first nominated by the United States in January 2006.

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 Montreal 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 2008, the Parties authorized the United States to allocate up to 385 MT of CFCs for essential uses. In the 2008 nomination for essential use allowances, the United States did not request CFCs for use in MDIs where the sole active ingredient is albuterol.

III. Essential Use Allowances for Medical Devices

The following is a step-by-step list of actions EPA and FDA have taken thus far to implement the exemption for medical devices found at section 604(d)(2) of the Act for the 2008 calendar year.

1. On January 17, 2007, EPA sent letters to MDI manufacturers requesting the following information under section 114 of the Act (''114 letters''):

a. The MDI product where CFCs will be used.

b. The number of units of each MDI product produced from 1/1/06 to 12/31/06.

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

[3] *See* Section 614(b) of the Act. EPA's regulations implementing the essential use provisions of the Act and the Protocol are located in 40 CFR part 82.

c. The number of units anticipated to be produced in 2007.

d. The number of units anticipated to be produced in 2008.

e. The gross target fill weight per unit (grams).

f. Total amount of CFCs to be contained in the MDI product for 2008.

g. The additional amount of CFCs necessary for production.

h. The total CFC request per MDI product for 2008.

The 114 letters are available for review in the Air Docket ID No. EPA–HQ–OAR–2007–0297. The companies requested that their responses be treated as confidential business information; for this reason, EPA has placed the responses in the confidential portion of the docket.

2. At the end of January 2007, as required by 40 CFR 82.13(u), EPA received information from MDI manufacturers that included such data as the type and quantity of CFCs held at the end of the year (i.e. stocks of pre-1996 and post-1996 CFCs). The data submitted in reports from each MDI manufacturer is available for review in the Air Docket ID No. EPA–HQ–OAR–2007–0297. The companies requested that their responses be treated as confidential business information; for this reason, EPA has placed the individual responses in the confidential portion of the docket.

3. On February 28, 2007, EPA sent FDA the information MDI manufacturers provided in response to the 114 letters and information required by 40 CFR 82.13(u) with a letter requesting that FDA make a determination regarding the amount of CFCs necessary for MDIs for calendar year 2008. This letter is available for review in Air Docket ID No. EPA–HQ–OAR–2007–0297.

4. On May 1, 2007 FDA sent a letter to EPA stating the amount of CFCs determined by the Commissioner to be necessary for each MDI company in 2008. This letter is available for review in the Air Docket ID No. EPA–HQ–OAR–2007–0297. FDA's letter informed EPA that it had determined that 27.0 MT of CFCs were medically necessary for use in MDIs in 2008. The letter stated: ''Our determination for the allocation of CFCs is lower than the total amount requested by sponsors. In reaching this estimate, we took into account the sponsors' production of MDIs that used CFCs as propellant in 2006, their estimated production in 2007, their estimated production in 2008, their anticipated essential-use allocations in 2007, and their current (as of December 31, 2006) stockpile levels. Our determination took into account any transferred CFCs as well as pre-1996 CFC amounts. We also considered the different types and blends of CFCs necessary to produce specific MDIs. Finally, we based our determination for 2008 on an estimate of the quantity of CFCs that would allow manufacturers to have a 12-month stockpile at the end of 2008 in accordance with paragraph 3 of Decision XVI/12 and paragraph 2 of Decision XVII/5.''

The letter stated that in making its determination, FDA made the following assumptions:

- All manufacturers will receive the full essential-use allocation proposed by EPA for calendar year 2007 (71 FR 64668, November 3, 2006);
- All manufacturers will procure the full quantity of CFCs allocated to them for calendar year 2007;
- The number of albuterol CFC MDIs produced in 2008 will be no more than half of the number produced in 2007, with albuterol HFA MDIs making up the remainder; and
- No bulk CFC currently held by, or allocated to, any manufacturer will be exported from the United States.

FDA's determination specified that the essential use allowances allocated for 2008 should only be used to acquire CFC–114 for the production of epinephrine MDIs. FDA's letter stated: ''In recent years, we aggregated the amounts for CFC–11, –12, and –114 and provided recommendations on the total amounts necessary to protect the public health. This year, as sponsors transition to non-CFC alternative and require smaller amounts of CFCs to produce CFC MDIs, we considered individual amounts of CFCs necessary to protect the public health and recommend an allocation of 27.0 tonnes of CFC–114 to Armstrong for the manufacture of epinephrine CFC MDIs.'' Consistent with FDA's determination letter, EPA is proposing to allocate 27.0 MT of CFC–114 to Armstrong for the production of epinephrine MDIs for 2008.

EPA has confirmed with FDA that this determination is consistent with Decision XVII/5, including language on stocks that states that Parties ''shall take into account pre- and post-1996 stocks of controlled substances as described in paragraph 1(b) of Decision IV/25, such that no more than a one-year operational supply is maintained by that manufacturer.'' In its analysis of a one-year operational supply of CFCs for the production of CFC-albuterol MDIs, FDA informed EPA that it calculates volumes to allow the manufacturer to end the calendar year with the appropriate stock of CFCs for essential uses. Allowing manufacturers to maintain up to a one-year operational supply accounts for unexpected variability in the demand for MDI products or other unexpected occurrences in the market and therefore ensures that MDI manufacturers are able to produce their essential use MDIs.

In accordance with the FDA determination, today's action proposes to allocate essential use allowances to Armstrong for a total of 27.0 MT of CFC–114 for the production of epinephrine MDIs only for calendar year 2008.

The amounts listed in this proposal are subject to additional review, and revision, by EPA and FDA if information demonstrates that the proposed allocations are either too high or too low. We specifically request comment on the extent to which the proposed allocation of CFCs is sufficient to protect public health and ensure the manufacture and continuous availability of CFCs necessary to meet the expected demand. We also request comment on whether the proposed allocation, when considered along with current stocks, will best protect consumers by providing a smooth transition to non-CFC alternatives. Commenters requesting increases or decreases of essential use allowances should provide detailed information supporting a claim for additional or fewer CFCs. Any company that needs less than the full amount listed in this proposal should notify EPA of the actual amount needed.

IV. Proposed Allocation of Essential Use Allowances for Calendar Year 2008

TABLE I.—ESSENTIAL USE ALLOWANCES FOR CALENDAR YEAR 2008

Company	Chemical	2008 Quantity (metric tons)
(i) Metered Dose Inhalers (for oral inhalation) for Treatment of Asthma and Chronic Obstructive Pulmonary Disease		
Armstrong Pharmaceuticals	CFC–114 (production of epinephrine MDIs only)	27.0

EPA proposes to allocate essential use allowances for calendar year 2008 to the entity listed in Table I. These allowances are for the production or import of the specified quantity of Class I controlled substances solely for the specified essential use.

V. 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 EO 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action.

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

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 propose 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

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

For purposes of assessing the impact of today's proposed rule on small entities, small entity is 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 which is independently owned and operated and is not dominant its field.

After considering the economic impacts of today's proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any significant adverse economic impact on small entities, since the primary purpose of the regulatory flexibility analyses is to identify and address regulatory alternatives ''which minimize any significant economic impact of the rule on small entities.'' 5 U.S.C. 603 and 604. Thus, an agency may certify 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 action, once finalized, will provide an otherwise unavailable benefit to those companies that are receiving essential use allowances by creating an exemption to the regulatory phaseout of chlorofluorocarbons. We have therefore concluded that today's proposed rule will relieve regulatory burden for all small entities. We continue to be interested in the potential impact of the proposed rule on small entities and welcome comments on issues related to such impacts.

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 proposed 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 proposed 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 proposed rule does not have tribal implications, as specified in Executive Order 13175. Today's proposed 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'' under Executive Order 12866, and (2) concerns an environmental health or 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 as the analysis required under section 5–501 of the Order has the potential to influence the regulation. This proposed rule is not subject to Executive Order 13045 because it implements Section 604(d)(2) of the Clean Air Act which states that the Agency shall authorize essential use exemptions should the Food and Drug Administration determine that such exemptions are necessary.

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

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

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629 (February 16, 1994)) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this proposed rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because any change in the level of environmental protection for any affected populations will not have any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population. Any impacts of this proposed rule will be equally distributed among all populations.

List of Subjects in 40 CFR Part 82

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

Dated: June 6, 2007.

Stephen L. Johnson,

Administrator.

40 CFR part 82 is proposed to be amended as follows:

PART 82—PROTECTION OF STRATOSPHERIC OZONE

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

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

Subpart A—Production and Consumption Controls

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

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

(a) * * *

TABLE I.—ESSENTIAL USE ALLOWANCES FOR CALENDAR YEAR 2008

Company	Chemical	2008 Quantity (metric tons)
(i) Metered Dose Inhalers (for oral inhalation) for Treatment of Asthma and Chronic Obstructive Pulmonary Disease		
Armstrong Pharmaceuticals	CFC–114 (production of epinephrine MDIs only)	27.0

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