course review and submit the results to EPA by December 31, 2003.

Due to challenges by upwind states of EPA's Regional NO_X Program, the benefit of these upwind NO_X reductions will not be fully realized until late 2003. Therefore, EPA has allowed states to revise their mid-course commitments to provide for the review no later than December 31, 2004. In order to be consistent with surrounding states and to include the benefit of the Regional NO_X Program in its mid-course review, New York revised its commitment to perform a mid-course review to December 31, 2004. EPA proposes to approve this revised commitment.

8. Summary of Conclusions and Proposed Action

This action is being proposed under a procedure called parallel processing, whereby EPA proposes rulemaking action concurrently with the State's procedures for amending its regulations. If the proposed revision is substantially changed in areas other than those identified in this document, EPA will evaluate those changes and may publish another notice of proposed rulemaking. If no substantial changes are made other than those areas cited in this document, EPA will publish a final rulemaking on the revisions. The final rulemaking action by EPA will occur only after the SIP revision has been adopted by New York and submitted formally to EPA for incorporation into the SIP.

EPA is proposing to approve New York's proposed SIP revision submitted on January 29, 2003. This submittal revises New Jersey's 1990 and 2007 motor vehicle emission budgets using MOBILE6 and modifies the planned date to complete the State's mid-course review to December 31, 2004. New York has demonstrated that its 1-Hour Attainment Demonstration SIP for the New York Metropolitan NAA continues to demonstrate attainment with the revised MOBILE6 budgets.

9. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this proposed action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This proposed action merely proposes to approve state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule proposes to approve pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4).

This proposed rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does 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 (64 FR 43255, August 10, 1999). This action merely proposes to approve a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This proposed rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This proposed rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: October 15, 2003.

Jane M. Kenny,

Regional Administrator, Region 2.

[FR Doc. 03–27157 Filed 10–27–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[FRL–7579–7]

Protection of Stratospheric Ozone: Allocation of Essential Use Allowances for Calendar Year 2004

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to allocate essential use allowances for import and production of class I stratospheric ozone depleting substances (ODSs) for calendar year 2004. 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 proposed allocations total 2077.91 metric tons of chlorofluorocarbons for use in metered dose inhalers. EPA is also proposing to allocate the remaining allowances for methyl chloroform (141.877 metric tons) to the U.S. Space Shuttle Program.

DATES: Written comments on this proposed rule must be received by the EPA Docket on or before November 28, 2003, 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 November 7, 2003. If a hearing is held, EPA will publish a document in the Federal Register announcing the hearing information.

ADDRESSES: Comments on this proposed rulemaking should be submitted to Air and Radiation Docket, Environmental

Protection Agency, Mailcode 6102T, 1200 Pennsylvania Ave., NW., Washington, DC, 20460, Attention: Docket ID No. OAR–2003–0202. Comments also may be submitted electronically, by facsimile, or through hand deliver or courier service, as described in **SUPPLEMENTARY INFORMATION** below. Comments will be filed in EPA Air Docket ID No. OAR–2003–0202. Written comments or other materials also may be submitted in duplicate to the Essential Use Program Manager as identified in **FOR FURTHER INFORMATION CONTACT** below.

Materials related to previous EPA actions on the essential use program are contained in EPA Air Docket No. A–93–39. Docket A–93–39 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.

FOR FURTHER INFORMATION CONTACT: Scott Monroe, Essential Use Program Manager, by regular mail: U.S. Environmental Protection Agency, Global Programs Division (6205J), 1200 Pennsylvania Avenue, NW., Washington, DC, 20460; by courier service or overnight express: 1301 L Street, NW., Washington DC, 20005, by telephone: 202–564–9712; or by email: *monroe.scott@epa.gov.*

SUPPLEMENTARY INFORMATION:

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I. General Information

A. 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–2003–0202. 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, although this information is part of EPA's official docket. 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) 566–1742, 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 submit or 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.

Certain types of information will not be placed in EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in section I.A.1 above.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the Docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

B. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, by facsimile, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in section I.C below. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. Electronically

Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket*, and follow the online instructions for submitting comments.

To access EPA's electronic public docket from the EPA Internet Home Page, select ''Information Sources,'' ''Dockets,'' and ''EPA Dockets.'' Once in the system, select ''search,'' and then key in Docket ID No. OAR–2003–0202. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

If you submit a comment electronically, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment. Any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket and made available in EPA's electronic public docket. 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.

Comments also may be sent by electronic mail (e-mail) to *A–And–R–Docket@epa.gov*, Attention Docket ID No. OAR–2003–0202. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the Docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

You may submit comments on a disk or CD ROM that you mail to the mailing address identified below. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. By Mail

Send two copies of your comments to: Air and Radiation Docket, Environmental Protection Agency, Mailcode 6102T, 1200 Pennsylvania Ave., NW., Washington, DC, 20460, Attention: Docket ID No. OAR–2003–0202.

3. By Hand Delivery or Courier

Deliver your comments to: EPA Docket Center, (EPA/DC) EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC, Attention Docket ID No. OAR–2003–0202. Such deliveries are only accepted during the Docket's normal hours of operation as identified in section I.A.1.

4. By Facsimile

Fax your comments to: 202–566–1741, Attention: Docket ID No. OAR–2003–0202.

C. How Should I Submit Confidential Business Information to EPA?

Comments that contain confidential business information should be submitted in two versions, one clearly marked ''Public'', to be filed in the public docket, and the other clearly marked ''Confidential'' to be reviewed by authorized government personnel only. If the comments are not marked, EPA will assume they do not contain confidential business information and will docket them.

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. Send or deliver information identified as CBI only to the Essential Use Program Manager. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, 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 CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2.

In addition to one complete version of the comment that includes any 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 and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

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 the international agreement to reduce and eventually eliminate the production and consumption [1] of all stratospheric ozone depleting substances (ODSs). The elimination of production and consumption of class I ODSs is accomplished through adherence to phase-out schedules for specific class I ODSs,[2] 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 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

[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). Stockpiles of class I ODSs produced or imported prior to the 1996 phase out may be used for purposes not expressly banned at 40 CFR part 82.

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

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.[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.'' EPA issues 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, 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 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.

The Protocol, under Decision X/19, additionally allows a general exemption for laboratory and analytical uses through December 31, 2005. 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 may 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 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 2001.

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 medical devices, EPA requests information from manufacturers about the number and type of devices 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 metered-dose inhalers in the coming calendar year. Based on FDA's assessment, 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 may not allocate essential use allowances in amounts higher than the total approved by the Parties. For 2004, the Parties authorized the United States to allocate up to 2,975 metric tons of CFCs for essential uses.

For methyl chloroform, Decision X/6 by the Parties to the Protocol established that ''* * * the remaining quantity of methyl chloroform authorized for the United States at previous meetings of the Parties [will] be made available for use in manufacturing solid rocket motors until such time as the 1999–2001 quantity of 176.4 tons (17.6 ODP-weighted tons) allowance is depleted, or until such time as safe alternatives are implemented for remaining essential uses.'' Section 604(d)(1) of the Act terminates the exemption period for methyl chloroform on January 1, 2005. Therefore, between 1999 and 2004 EPA may allow production or import up to a total of 176.4 metric tonnes of methyl chloroform for authorized essential uses.

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 2004 control period.

1. On March 10, 2003, 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 1/1/02 to 12/31/02.

c. The number of units anticipated to be produced in 2003.

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

e. Total amount of CFCs to be contained in the MDI product for 2004.

f. The additional amount of CFCs necessary for production.

g. The total CFC request per MDI product for 2004. The 114 letters are available for review in the Air Docket ID No. OAR–2003–0202. The companies requested that their responses be treated as confidential business information; for

[3] According to Section 614(b) of the Act, Title VI ''shall be construed, interpreted, and applied as a supplement to the terms and conditions of the Montreal Protocol * * * and shall not be construed, interpreted, or applied to abrogate the responsibilities or obligations of the United States to implement fully the provisions of the Montreal Protocol. In the case of conflict between any provision of this title and any provision of the Montreal Protocol, the more stringent provision shall govern.'' EPA's regulations implementing the essential use provisions of the Act and the Protocol are located in 40 CFR part 82.

this reason, EPA has not placed the responses in the docket.

2. On April 17, 2003, EPA sent FDA the information MDI manufacturers provided in response to the 114 letters with a letter requesting that FDA make a determination regarding the amount of CFCs necessary for MDIs for calendar year 2003. This letter is available for review in Air Docket ID No. OAR–2003–0202.

3. On August 25, 2003, FDA sent a letter to EPA stating the amount of CFCs necessary for each MDI company in 2004. This letter is available for review in the Air Docket ID No. OAR–2003–0202.

In their letter, FDA informed EPA that they had determined that 2,077.91 metric tons of CFCs were necessary for use in medical devices in 2004. The letter stated, ''Our recommendation for the allocation for CFCs is lower than the total amount requested by sponsors. In the past, we have based our recommendations on estimates that 60 million albuterol MDIs using CFCs as a propellant would be necessary each year. However, we have based the recommendation for 2004 on an estimate that 55 million will be necessary. In reaching this estimate, we took into account the sponsors' production of albuterol MDIs that used CFCs as a propellant in 2002, their estimates for production in 2003, and the presence on the market of two albuterol MDIs that do not use CFCs. Three firms have requested CFCs sufficient to manufacture a total of over 65 million albuterol MDIs. Our allocation decision is based on a need to limit CFC allocations to quantities needed for the manufacture of 55 million albuterol MDIs and ensure the public health.''

In accordance with the determination made by FDA, today's action proposes to allocate essential use allowances for a total of 2,077.91 metric tons of CFCs for use in MDIs for calendar year 2004. The amounts listed in this proposal are subject to additional review by EPA and FDA if new information demonstrates that the proposed allocations are either too high or too low. Commentors requesting increases or decreases of essential use allowances should provide detailed information supporting their 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. Exemption for Methyl Chloroform for Use in the Space Shuttle and Titan Rockets

As discussed in Section I.C above, before the start of calendar year 2005; EPA may allocate up to 176.4 tons of methyl chloroform for authorized essential uses. According to reporting submitted to the EPA tracking system for ozone-depleting substances, the total amount of methyl chloroform produced or imported by essential use allowance holders (the U.S. Air Force (USAF) for Titan Rockets, and the National Aeronautics and Space Administration (NASA) for the Space Shuttle) from 1999 through the second quarter of 2003 was 34.523 metric tons. USAF and NASA have notified EPA that they do not intend to use their 2003 allowances to obtain methyl chloroform during the last two quarters of 2003. Therefore, EPA finds that 141.877 tons of methyl chloroform allowances are available for 2004. In addition, USAF has notified EPA that they have no need for 2004 allowances. For this reason, we propose to make the remaining balance of allowances (141.877 metric tons) available to NASA.

V. Proposed Allocation of Essential Use Allowances for Calendar Year 2004

EPA proposes to allocate essential use allowances for calendar year 2004 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 2004

Company	Chemical	Quantity (metric tons)
(i) 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	390.60
Aventis Pharmaceutical Products	CFC–11 or CFC–12 or CFC–114	48.40
Boehringer Ingelheim Pharmaceuticals	CFC–11 or CFC–12 or CFC–114	500.20
PLIVA Inc.	CFC–11 or CFC–12 or CFC–114	136.00
Schering-Plough Corporation	CFC–11 or CFC–12 or CFC–114	918.00
3M Pharmaceuticals	CFC–11 or CFC–12 or CFC–114	84.71
(ii) Cleaning, Bonding and Surface Activation Applications for the Space Shuttle Rockets and Titan Rockets		
National Aeronautics and Space Administration (NASA)/ Thiokol Rocket.	Methyl Chloroform	141.877

VI. Correction to 40 CFR Part 82, Sections 3 and 4(k)

On January 2, 2003, EPA published a final rule (68 FR 237) regarding quarantine and preshipment applications of methyl bromide, which is an ozone-depleting substance. This final rule removed paragraphs (n) through (s) of 40 CFR Part 82, Section 4, and redesignated paragraphs (t) through (w) as (n) through (q). However, the final rule did not also change the definition of ''essential-use allowances'' in § 82.3 to be consistent with the reordering of paragraphs in § 82.4. The definition of essential use allowances in § 82.3 reads, ''Essential-Use Allowances means the privileges granted by § 82.4(t) to produce class I substances, as determined by allocation decisions made by the Parties to the Montreal Protocol and in accordance with the restrictions delineated in the Clean Air Act Amendments of 1990.'' Therefore, for consistency with the reordered regulations, we are correcting the definition of essential use allowances to refer to § 82.4(n).

In addition, the final rule revised section 4(k) of 40 CFR Part 82 to include paragraph 4(k)(1), which states that ''* * * only essential-use allowances or exemptions are required to import class I controlled substances, with the exception of transhipments, heels, and used controlled substances.'' In undertaking this revision, EPA inadvertently deleted a phrase that had appeared in the prior version of this statement. EPA proposes to restore the deleted phrase by correcting the statement in question to read, ''* * * only essential use allowances or exemptions are required to import class I controlled substances, with the

exception of transhipments, heels, used controlled substances, and essential use CFCs.'' This correction clarifies that the import restriction does not apply to CFCs produced by non-U.S. entities under the authority of privileges granted by the Parties and the national authority of another country for use in essential metered dose inhalers. *See* 67 FR 6351 (February 11, 2002).

VII. 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.

It has been determined that this action is not a ''significant regulatory action'' under the terms of Executive Order 12866 and is therefore not subject to OMB review.

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

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 rule on small entities, the term small entities 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. This rule provides an otherwise unavailable benefit to those companies that are receiving essential use allowances.

Although this proposed rule will not have significant economic impact on a substantial number of small entities, we continue to be interested in the potential impact of the proposed rule on small entities and welcome comments related to these issues.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year.

Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective, or least burdensome alternative, if the Administrator publishes with the final rule an explanation why that alternative was not adopted.

Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed a small government agency plan under section 203 of the UMRA. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local, or tribal governments or the private sector, since it merely provides exemptions from the 1996 phase out of class I ODSs. Similarly, EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments, because this rule merely allocates essential use exemptions to entities as an exemption to the ban on production and import of class I ODSs.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State

and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

This 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 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 E.O. 12866, and (2) concerns an environmental health and safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency. EPA interprets E.O. 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5–501 of the Order has the potential to influence the regulation. This rule is not subject to E.O. 13045 because it implements the phase-out 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 a significant regulatory action under Executive Order 12866.

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.

List of Subjects in 40 CFR Part 82

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

Dated: October 22, 2003.

Marianne L. Horinko,

Acting 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 82.3 is amended by revising the definition of Essential Use Allowances to read as follows:

§ 82.3 Definitions for class I and class II controlled substances.

* * * * *

Essential-Use Allowances means the privileges granted by § 82.4(n) to produce class I substances, as determined by allocation decisions made by the Parties to the Montreal Protocol and in accordance with the restrictions delineated in the Clean Air Act Amendments of 1990.

* * * * *

3. Section 82.4 is amended by revising paragraph (k)(1) and the table in paragraph (n)(2) to read as follows:

§ 82.4 Prohibitions for class I controlled substances.

* * * * *

(k)(1) Prior to January 1, 1996, for all Groups of class I controlled substances, and prior to January 1, 2005, for class I, Group VI controlled substances, a person may not use production allowances to produce a quantity of a class I controlled substance unless that person holds under the authority of this subpart at the same time consumption allowances sufficient to cover that quantity of class I controlled substances nor may a person use consumption allowances to produce a quantity of class I controlled substances unless the person holds under authority of this subpart at the same time production allowances sufficient to cover that quantity of class I controlled substances. However, prior to January 1, 1996, for all class I controlled substances, and prior to January 1, 2005, for class I, Group VI controlled substances, only consumption allowances are required to import, with the exception of transhipments, heels, and used controlled substances. Effective January 1, 1996, for all Groups of class I controlled substances, except Group VI, only essential use allowances or exemptions are required to import class I controlled substances, with the exception of transhipments, heels, used controlled substances, and essential use CFCs.

* * * * *

(n) * * *

(2) * * *

TABLE I.—ESSENTIAL USE ALLOCATION FOR CALENDAR YEAR 2004

Company	Chemical	Quantity (metric tons)
(i) 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	390.60
Aventis Pharmaceutical Products	CFC–11 or CFC–12 or CFC–114	48.40
Boehringer Ingelheim Pharmaceuticals	CFC–11 or CFC–12 or CFC–114	500.20
PLIVA Inc.	CFC–11 or CFC–12 or CFC–114	136.00
Schering-Plough Corporation	CFC–11 or CFC–12 or CFC–114	918.00
3M Pharmaceuticals	CFC–11 or CFC–12 or CFC–114	84.71
(ii) Cleaning, Bonding and Surface Activation Applications for the Space Shuttle Rockets		
National Aeronautics and Space Administration (NASA)/ Thiokol Rocket.	Methyl Chloroform	141.877

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