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[FR Doc. 04–27985 Filed 12–21–04; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[FRL–7852–1]

RIN 2060–AM50

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

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 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 proposed allocations total 1,524.58 metric tons of chlorofluorocarbons for use in metered dose inhalers.

DATES: Written comments on this proposed rule must be received by the EPA Docket on or before January 21, 2005, 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 January 23, 2005. If a hearing is held, EPA will publish a document in the **Federal Register** announcing the hearing information.

ADDRESSES: Submit your comments, identified by Docket ID No. OAR–2004–0063, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Agency Web site: http://www.epa.gov/edocket.* EDOCKET, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Follow the on-line instructions for submitting comments.
- *Mail:* Air and Radiation Docket, Environmental Protection Agency, Mailcode 6102T, 1200 Pennsylvania Ave., NW., Washington, DC, 20460, Attention: Docket ID No. OAR–2004–0063.
- *Hand Delivery:* EPA Docket Center, (EPA/DC) EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC, Attention Docket ID No. OAR–2004–0063. 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 Air Docket ID No. OAR–2004–0063. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.epa.gov/edocket*, 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 that you consider to be CBI or otherwise protected through EDOCKET, regulations.gov, or e-mail. For instructions on how to submit CBI, see ''How do I submit confidential business information to EPA?'' under **SUPPLEMENTARY INFORMATION.**

The EPA EDOCKET and the federal regulations.gov websites are ''anonymous access'' systems, 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 EDOCKET or *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.

Docket: All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, namely CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Air Docket, EPA/DC, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for Docket ID No. OAR–2004–0063 is (202) 566–1742.

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 may be reviewed at the Public Reading Room.

FOR FURTHER INFORMATION CONTACT: Scott Monroe, Essential Use Program Manager, 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., Washington D.C., 20005, by telephone: 202–343–9712; or by e-mail: *monroe.scott@epa.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. General Information

A. 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 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 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.'' 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.'' Prior to 2004, EPA issued allowances for production of approximately 34 metric tons of methyl chloroform out of the authorized balance of 176 metric tons. Under section 604(d)(1) of the Act, EPA may no longer allocate essential use allowances for production and import of methyl chloroform as of January 1, 2005. In light of this deadline, in the allocation rulemaking for calendar year 2004 (69 FR 4059) EPA allocated the remaining authorized production allowances for methyl chloroform, approximately 142 metric tons, to the National Aeronautics and Space Administration.

(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

[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.

[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.

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. 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 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 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 2005, the Parties authorized the United States to allocate up to 1,902 metric tons of CFCs for 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 2005 control period.

1. On February 24, 2004, 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 1/1/03 to 12/31/03.

c. The number of units anticipated to be produced in 2004.

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

e. Total amount of CFCs to be contained in the MDI product for 2005.

f. The additional amount of CFCs necessary for production.

g. The total CFC request per MDI product for 2005.

The 114 letters are available for review in the Air Docket ID No. OAR–2004–0063. The companies requested that their responses be treated as confidential business information; for this reason, EPA has not placed the responses in the docket.

2. On May 18, 2004, 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 2005. This letter is available for review in Air Docket ID No. OAR–2004–0063.

3. On July 28, 2004, FDA sent a letter to EPA stating the amount of CFCs determined by the Commissioner to be necessary for each MDI company in 2005. This letter is available for review in the Air Docket ID No. OAR–2004–0063. In their letter, FDA informed EPA that they had determined that 1524.58 metric tons of CFCs were necessary for use in medical devices in 2005.

In accordance with the determination made by FDA, today's action proposes to allocate essential use allowances for a total of 1524.58 metric tons of CFCs for use in MDIs for calendar year 2005. 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. Proposed Allocation of Essential Use Allowances for Calendar Year 2005

EPA proposes to allocate 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. As explained in Section II.C. above, the amount of each allocation is based on the request of the company, which was reviewed by FDA to determine the quantities necessary for use in medical devices.

TABLE I.—ESSENTIAL USE ALLOCATION FOR CALENDAR YEAR 2005

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	29
Aventis Pharmaceutical Products	CFC–11, or CFC–12, or CFC–114	57
Boehringer Ingelheim Pharmaceuticals	CFC–11, or CFC–12, or CFC–114	480
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	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, OMB has notified EPA that it considers this a ''significant regulatory action'' within the meaning of the Executive Order. EPA submitted this action to OMB for review and incorporated changes as a result. A copy of the rule showing changes that were made is available in EPA Docket OAR–2004–0063.

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 proposed 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 proposed 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 proposed 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.* MB 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, 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 in 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 rule provides 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), Pub. L. 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. Today's rule affects only the companies that requested essential use allowances. 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 Fed. Reg. 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.

List of Subjects in 40 CFR Part 82

Administrative practice and procedure, Air pollution control, Chemicals, Chlorofluorocarbons, Environmental protection, Imports,

Methyl Chloroform, Ozone, Reporting and recordkeeping requirements.

Dated: December 16, 2004.

Michael O. Leavitt,

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 82.4 is amended by revising the table in paragraph (n)(2) to read as follows:

§ 82.4 Prohibitions for class I controlled substances.

* * * * *

(n) * * *

(2) * * *

TABLE I.—ESSENTIAL USE ALLOCATION FOR CALENDAR YEAR 2005

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	29
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Boehringer Ingelheim Pharmaceuticals	CFC–11, or CFC–12, or CFC–114	480
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	CFC–11, or CFC–12, or CFC–114	73.40

* * * * *

[FR Doc. 04–27994 Filed 12–21–04; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF STATE

48 CFR Parts 619, 625, 628, and 652

[Public Notice 4938]

RIN 1400–AB90

Department of State Acquisition Regulation

AGENCY: State Department.

ACTION: Proposed rule.

SUMMARY: This proposed rule makes three changes to the DOSAR. It revises the DOSAR to: Formalize Department policy regarding the application of the Small Business Act to contracts awarded by domestic contracting activities where contract performance takes place overseas; add language to deal with U.S. Government support to contractors performing overseas; and, revise the coverage regarding Defense Base Act insurance.

DATES: The Department will accept comments from the public up to 60 days from December 22, 2004.

ADDRESSES: You may submit comments, identified by any of the following methods:

- *E-mail: ginesgg@state.gov*. You must include the RIN in the subject line of your message.
- *Mail (paper, disk, or CD–ROM submissions):* Gladys Gines, Procurement Analyst, Department of State, Office of the Procurement Executive, 2201 C Street, NW., Suite 603, State Annex Number 6, Washington, DC 20522–0602.
- *Fax:* 703–875–6155.

Persons with access to the Internet may also view this notice and provide comments by going to the *regulations.gov* Web site at: *http://www.regulations.gov/index.cfm*.

FOR FURTHER INFORMATION CONTACT: Gladys Gines, Procurement Analyst, Department of State, Office of the Procurement Executive, 2201 C Street, NW., Suite 603, State Annex Number 6, Washington, DC 20522–0602; e-mail address: *ginesgg@state.gov*.

SUPPLEMENTARY INFORMATION: As indicated in the Summary, the proposed rule makes three changes to the DOSAR, as follows:

- DOSAR 619.000 is added to formalize the Department's policy regarding the application of the Small Business Act to contracts awarded by domestic contracting activities (*i.e.*, those located in the United States) where contract performance takes place overseas. Currently, FAR 19.000(b) states that part 19, with the exception of subpart 19.6, applies ''only in the United States or its outlying areas.'' This language is ambiguous and subject to interpretation. While the application is clear with respect to contracts both awarded and performed in the United States (it applies) and to contracts both awarded and performed outside the United States (it does not apply), the gray area is its applicability to contracts awarded by contracting offices located in the United States but where contract performance takes place overseas. The Department has subsequently followed an informal policy of applying part 19 to such contracts. This DOSAR change, therefore, states this policy in explicit terms.
- A new DOSAR subpart 625.71 is added to address the issue of the Department's administrative, logistical, and security support of contractor personnel performing overseas in locations where a contingency operation is ongoing or in high-risk locations. Essentially, the policy requires that contractors furnish their own in-country non-U.S. Government administrative, logistical, and security support. If the Department authorizes the use of U.S. Government-provided support, that support shall be set forth in the Statement of Work. An associated contract clause is added at 652.225–72. The clause is mandatory in Department contracts when the contract is in support of the operations/missions at one or more U.S. diplomatic or consular missions, and the location of the U.S. diplomatic or consular mission at which the work is to be performed is designated as a contingency operation, as defined in FAR 2.101. The clause is optional for use in contracts in support of the operations/missions at one or more U.S. diplomatic or consular missions in situations where a military contingency operation does not exist, but a high risk to personnel or property is known or anticipated.
- Subpart 628.3 is revised to clarify the application of Defense Base Act (DBA) insurance to local and third country nationals. The Department of