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 rulemaking 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

Environmental protection, Administrative practice and procedure, Chemicals, Exports, Halon, Imports, Ozone Layer, Reporting and recordkeeping requirements.

Dated: April 5, 2006.

Stephen L. Johnson,

Administrator.

[FR Doc. 06–3462 Filed 4–10–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[EPA–HQ–OAR–2006–0158; FRL–8157–3]

RIN 2060–AN29

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

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 2006. 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 ODS solely for the designated essential purpose. The proposed allocations total 1,002.40 metric tons of chlorofluorocarbons (CFCs) for use in metered dose inhalers for 2006.

DATES: Written comments on this proposed rule must be received by the EPA Docket on or before May 11, 2006, unless a public hearing is requested. Comments must then be received on or before May 22, 2006. 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 April 17, 2006. If a hearing is held, it will take place on April 21, 2006 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–2006–0158, by one of the following methods:

- *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
- E-mail: *A-and-R-docket@epa.gov*
- Fax: 202–343–2337, attn: Hodayah Finman
- Mail: Air Docket, Environmental Protection Agency, Mailcode 6102T, 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 B108, Mail Code 6102T, Washington, D.C. 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–2006–0158. 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.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 that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://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 *http://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 *http://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 *http://www.regulations.gov* or in hard copy at the Air Docket, EPA/DC, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. This Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The 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: Hodayah Finman, Team Leader, 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 827M Washington DC 20005, by telephone: 202–343–9246; or by e-mail: *finman.hodayah@epa.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. General Information

A. What Should I Consider When Preparing My Comments?

1. Confidential Business Information

Do not submit this information to EPA through *http://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 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 aimed at reducing and eliminating the production and consumption of stratospheric ozone-depleting substances. The elimination of production and consumption of class I ODSs is accomplished through adherence to phase-out schedules for specific class I ODSs [1], 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.[2] Section 604(d) of the Act authorizes EPA to allow the production of limited quantities of class I ODSs after the phase out date for the following essential uses:

(1) Methyl Chloroform, ''solely for use in essential applications (such as nondestructive testing for metal fatigue and corrosion of existing airplane engines and airplane parts susceptible to metal fatigue) for which no safe and effective substitute is available.'' Under section 604(d)(1) of the Act, this exemption was available only until January 1, 2005.

(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. 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

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

[2] 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.

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). 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.

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 2004.

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 2006, the Parties authorized the United States to allocate up to 1,100 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 2006 control period.

1. On March 24, 2005, 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 1/1/04 to 12/31/04.

c. The number of units anticipated to be produced in 2005.

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

e. Total amount of CFCs to be contained in the MDI product for 2006.

f. The additional amount of CFCs necessary for production.

g. The total CFC request per MDI product for 2006.

The 114 letters are available for review in the Air Docket ID No. EPA–HQ–OAR–2006–0158. 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 July 5, 2005, 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 2006. This letter is available for review in Air Docket ID No. EPA–HQ–OAR–2006–0158.

3. On October 12, 2005, FDA sent a letter to EPA stating the amount of CFCs determined by the Commissioner to be necessary for each MDI company in 2006. This letter is available for review in the Air Docket ID No. EPA–HQ–OAR–2006–0158. In their letter, FDA informed EPA that they had determined that 1,002.40 metric tons of CFCs were necessary for use in medical devices in 2006. The letter stated: ''Our recommendation 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 a propellant in 2004, their estimated production in 2005, their estimated production in 2006, their current stockpile levels, and the presence on the market of two albuterol MDIs that do not use CFCs. We have also based our recommendation for 2006 on an estimate of the quantity of MDIs using CFCs as a propellant that would be necessary for sponsors to maintain a 12-month stockpile, consistent with paragraph 3 of Decision XVI/12.'' EPA has confirmed with FDA that this determination is consistent with Decision XVII/5, including new 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 accordance with the determination made by FDA, today's action proposes to allocate essential use allowances for a total of 1,002.40 metric tons of CFCs for use in MDIs for calendar year 2006.

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 2006

TABLE I.—ESSENTIAL USE ALLOCATION FOR CALENDAR YEAR 2006

Company	Chemical	2006 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	147.50
Boehringer Ingelheim Pharmaceuticals	CFC–11 or CFC–12 or CFC–114	116.50
Inyx (Aventis)	CFC–11 or CFC–12 or CFC–114	106.40
Schering-Plough Corporation	CFC–11 or CFC–12 or CFC–114	556.00
3M Pharmaceuticals	CFC–11 or CFC–12 or CFC–114	0.0

TABLE I.—ESSENTIAL USE ALLOCATION FOR CALENDAR YEAR 2006—Continued

Company	Chemical	2006 Quantity (metric tons)
Wyeth	CFC–11 or CFC–12 or CFC–114	76.0

EPA proposes to allocate essential use allowances for calendar year 2006 to the entities listed in Table 1. These allowances are for the production or import of the specified quantity of class I controlled substances solely for the specified essential use.

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.

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

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 2006. 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 proposed 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 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 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, EPA certifies 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 proposed 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 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 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'' under E.O. 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 E.O. 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 E.O. 13045 because it implements a mandatory requirement as per Section 604(d)(2) of the Clean Air Act which compels the Agency to allocate essential use exemptions should the Food and Drug Administration finds that the exemption is 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 No. 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: April 5, 2006.

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 Grants of essential use allowances and critical use allowances.

(a) * * *

TABLE I.—ESSENTIAL USE ALLOCATION FOR CALENDAR YEAR 2006

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

* * * * *

[FR Doc. E6–5329 Filed 4–10–06; 8:45 am]

BILLING CODE 6560–50–P