

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 82**

[FRL-7876-1]

RIN 2060-AM50

**Protection of Stratospheric Ozone: Supplemental Proposal for the Allocation of Essential Use Allowances for Calendar Year 2005****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Supplemental notice of proposed rulemaking.

**SUMMARY:** This action supplements EPA's December 22, 2004, notice of proposed rulemaking (69 FR 76655). In proposing essential use allocations for calendar year 2005, EPA published an incorrect number for the quantity of controlled substances to be allocated to one company, Armstrong Pharmaceuticals. This supplemental proposed rule is being issued to correct the error by increasing Armstrong's allocation to equal the amount determined by the U.S. Food and Drug Administration (FDA) to be medically necessary in 2005. As a result of this action, the total allocations to all companies would be raised from 1524.58 metric tons, as originally proposed, to 1766.48 metric tons.

**DATES:** Written comments on this proposed rule must be received by the EPA Docket on or before March 25, 2005.

**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](http://www.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](http://www.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](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.

**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, DC 20005, by telephone: 202-343-9712; or by e-mail: [monroe.scott@epa.gov](mailto:monroe.scott@epa.gov).

**SUPPLEMENTARY INFORMATION:****I. What Is the Purpose of This Supplementary NPRM?**

The purpose of today's notice is to correct an error in the proposed rule that EPA published in the **Federal Register** of December 22, 2004 (69 FR 76655). That action proposed to allocate production and import allowances to Armstrong Pharmaceuticals for a quantity of controlled substances in the amount of 29 metric tons. The Food and Drug Administration (FDA), which determines the amount of controlled substances that are medically necessary in each control period, notified EPA via letter after the proposed rule appeared in the **Federal Register** that the proposed allocation for Armstrong Pharmaceuticals was incorrect (this letter is available in Air Docket OAR-2004-0063). The proposed amount should have been 270.90 metric tons.

EPA is therefore proposing to allocate to Armstrong Pharmaceuticals an additional quantity of production and import allowances in the amount of 241.90 metric tons, which represents the difference between the amount that FDA determined was necessary (270.90 metric tons) and the amount already proposed by EPA (29 metric tons). EPA is not proposing to alter any other company's allocation, as proposed on December 22, 2004, in today's action.

As a result of the previously published NPRM and today's supplemental NPRM, the total amount proposed to be allocated to Armstrong Pharmaceuticals for calendar year 2005 is 270.90 metric tons, and consequently the total amount allocated to all companies (including Armstrong) would be increased from 1,524.58 metric tons to 1,766.48 metric tons. The latter amount is less than the total amount, 1,902 metric tons, that was authorized to the United States for 2005 by the Parties to the Montreal Protocol.

The reader is referred to the December 22, 2004, NPRM for background information about the essential use program and the process by which EPA and FDA determined the proposed allocations for 2005.

## II. 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, 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 the company,

Armstrong Pharmaceuticals, that is 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 Armstrong Pharmaceuticals. We continue to be interested in the potential impact of the proposed rule on small entities and welcome comments on issues related to such impacts.

### D. Unfunded Mandates Reform Act

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

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

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

Today's 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 one company 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 one company that requested

essential use allowances. Thus, Executive Order 13175 does not apply to this rule.

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

Executive Order 13045, "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), applies to any rule that (1) is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health and safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency. EPA interprets Executive Order 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5-501 of the Order has the potential to influence the regulation. This rule is not subject to Executive Order 13045 because it implements the phaseout schedule and exemptions established by Congress in Title VI of the Clean Air Act.

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

This rule is not subject to Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The rule affects only one company 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: February 15, 2005.

**Stephen L. Johnson,**  
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 82.8 is amended by revising the table in paragraph (a) to read as follows:

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

(a) \* \* \*

TABLE I.—ESSENTIAL USE ALLOCATION FOR CALENDAR YEAR 2005

Company	Chemical	Quantity (metric tons)
<b>Metered Dose Inhalers (for oral inhalation) for Treatment of Asthma and Chronic Obstructive Pulmonary Disease</b>		
Armstrong Pharmaceuticals .....	CFC-11 or CFC-12 or CFC-114 .....	270.90
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
Wyeth .....	CFC-11 or CFC-12 or CFC-114 .....	73.40

\* \* \* \* \*

[FR Doc. 05-3451 Filed 2-22-05; 8:45 am]

BILLING CODE 6560-50-U

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 271**

[FRL-7875-6]

**Mississippi: Final Authorization of State Hazardous Waste Management Program Revisions****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Proposed rule.

**SUMMARY:** Mississippi has applied to EPA for Final authorization of the changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). EPA proposes to grant final authorization to Mississippi for RCRA Clusters IV through X. In the "Rules and Regulations" section of this **Federal Register**, EPA is authorizing the changes by an immediate final rule. EPA did not make a proposal prior to the immediate final rule because we believe this action is not controversial and do not expect comments that oppose it. We have explained the reasons for this authorization in the preamble to the immediate final rule. Unless we get written comments which oppose this authorization during the comment period, the immediate final rule will become effective on the date it establishes, and we will not take further action on this proposal. If we get comments that oppose this action, we will withdraw the immediate final rule and it will not take effect. We will then respond to public comments in a later final rule based on this proposal. You may not have another opportunity for comment. If you want to comment on this action, you must do so at this time.

**DATES:** Send your written comments by March 25, 2005.

**ADDRESSES:** Submit your comments by one of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- E-mail: [middlebrooks.gail@epa.gov](mailto:middlebrooks.gail@epa.gov).
- Fax: (404) 562-8439 (prior to faxing, please notify the EPA contact listed below).
- Mail: Send written comments to Gail Middlebrooks at the address listed below.

**Instructions:** Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov>, or e-mail. The Federal [regulations.gov](http://www.regulations.gov) Web site 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 comments. 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.

You can view and copy Mississippi's applications from 8 a.m. to 4:30 p.m. at the following addresses: Mississippi Department of Environmental Quality, Hazardous Waste Division, 101 W. Capital, Suite 100, Jackson, Mississippi 39201; and EPA, Region 4, Library, 9th Floor, The Sam Nunn Atlanta Federal Center, 61 Forsyth Street, SW., Atlanta, Georgia 30303-3104; (404) 562-8190.

**FOR FURTHER INFORMATION CONTACT:** Gail Middlebrooks, RCRA Services Section, RCRA Programs Branch, Waste Management Division, U.S. Environmental Protection Agency, Region 4, The Sam Nunn Atlanta Federal Center, 61 Forsyth Street, SW., Atlanta, Georgia 30303-3104; (404) 562-8494.

**SUPPLEMENTARY INFORMATION:** For additional information, please see the immediate final rule published in the "Rules and Regulations" section of this **Federal Register**.

Dated: February 2, 2005.

**A. Stanley Meilburg,**

*Acting Regional Administrator, Region 4.*

[FR Doc. 05-3364 Filed 2-22-05; 8:45 am]

BILLING CODE 6560-50-P

**DEPARTMENT OF TRANSPORTATION****Office of the Secretary****49 CFR Subtitle A**

[Docket No. OST-2005-20434]

**Driver's Licenses and Personal Identification Cards**

**AGENCY:** Office of the Secretary (OST), DOT.

**ACTION:** Notice of intent to form a negotiated rulemaking advisory committee.

**SUMMARY:** Pursuant to the portion of the Intelligence Reform and Terrorism Prevention Act of 2004 known as the 9/11 Commission Implementation Act of 2004, the Office of the Secretary, DOT, is establishing a committee to develop, through negotiated rulemaking procedures, recommendations for minimum standards to tighten the security for driver's licenses and personal identification cards issued by

States, in order for these documents to qualify for use by Federal agencies for identification purposes. The committee will consist of persons who represent the interests affected by the proposed rule, *i.e.*, State offices that issue driver's licenses or personal identification cards, elected State officials, the Departments of Transportation and Homeland Security, and other interested parties. The purpose of this document is to invite interested parties to submit comments on the issues to be discussed and the interests and organizations to be considered for representation on the committee.

**DATES:** You should submit your comments or applications for membership or nominations for membership on the negotiated rulemaking committee early enough to ensure that the Department's Docket Management System (DMS) receives them not later than March 25, 2005. Late-filed comments will be considered to the extent practicable.

**ADDRESSES:** You should mention the docket number of this document in your comments or application/nomination for membership and submit them in writing to: Docket Management System (DMS), Room PL-401, 400 Seventh Street, SW., Washington, DC 20590. Commenters may also submit their comments electronically. Instructions for electronic submission may be found at the following Web address: <http://dms.dot.gov/submit/>.

You may call the Docket at 202-366-9324, and visit it from 10 a.m. to 5 p.m., Monday through Friday. Interested persons may view docketed materials on the Internet at any time. Instructions for doing so are found at the end of this notice.

You may read the comments received by DMS at the address given above under **ADDRESSES**. The hours of the Docket are indicated above in the same location.

You may also review all documents in the docket via the internet. To read docket materials on the internet, take the following steps:

1. Go to the DMS Web page of the Department of Transportation (<http://dms.dot.gov/>).
2. On that page, click on "search."
3. On the next page (<http://dms.dot.gov/search/>), type in the four-digit docket number shown at the beginning of this document. Example: If the docket number were OST-2005-1234," you would type "1234." After typing the docket number, click on "search."
4. On the next page, which contains docket summary information for the