TABLE 4 TO SUBPART FFFFF OF PART 63.—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART FFFFF

Citation	Subject	Applies to Subpart FFFFF	Explanation	
* *	* *	*	* *	
§ 63.6(h)(2)(i)	Determining Compliance with Opacity and VE Standards.	No	Subpart FFFFF specifies methods and procedures for determining compliance with opacity emission and operating limits.	
* *	* *	*	* *	
§ 63.8(a)(1)-(3), (b), (c)(1)-(3), (c)(4)(i)-(ii), (c)(5)-(6), (c)(7)-(8), (f)(1)-(5), (g)(1)-(4).			CMS requirements in §§ 63.8(c)(4)(i)— (ii), (c)(5)–(6), (d), and (e) apply only to COMS.	
§ 63.8(a)(4)	Additional Monitoring Requirements for Control Devices in § 63.11.	No	Subpart FFFFF does not require flares.	
§ 63.8(c)(4)		No	Subpart FFFFF specifies requirements for operation of CMS.	
§ 63.8(f)(6)		No.		
§ 63.8(g)(5)	Data Reduction	No	Subpart FFFFF specifies data reduction requirements.	
§ 63.9	Notification Requirements	Yes	Additional notifications for CMS in §63.9(g) apply only to COMS.	
$ \begin{array}{lll} \S 63.10(a), & (b)(1), & (b)(2)(i)-(xii), \\ (b)(2)(xiv), & (b)(3), & (c)(1)-(6), & (c)(9)- \\ (15), & (d), & (e)(1)-(2), & (e)(4), & (f) \end{array} $	Recordkeeping and Reporting Requirements.	Yes	Additional records for CMS in §63.10(c)(1)–(6), (9)–(15), and reports in §63.10(d)(1)–(2) apply only to COMS.	
§ 63.10(b)(2) (xiii)	CMS Records for RATA Alternative Records of Excess Emissions and Pa- rameter Monitoring Exceedances for CMS.	No. No	Subpart FFFFF specifies record requirements.	
§ 63.10(e)(3)	Excess Emission Reports	No	Subpart FFFFF specifies reporting requirements.	
*	* *	*	* *	

[FR Doc. 05–17193 Filed 8–29–05; 8:45 am] BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[FRL-7962-3]

RIN 2060-AN13

Protection of Stratospheric Ozone: Process for Exempting Critical Uses of Methyl Bromide for the 2005 Supplemental Request

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed rulemaking.

SUMMARY: With this action EPA is proposing to authorize use of 610,665 kilograms of methyl bromide for supplemental critical uses in 2005 through the allocation of additional critical stock allowances (CSAs). This allocation would supplement the critical use allowances (CUAs) and CSAs previously allocated for 2005, as published in the Federal Register on December 23, 2004 (69 FR 76982). Further, EPA is proposing to amend the existing list of exempted critical uses.

With today's action EPA is proposing to exempt methyl bromide for critical uses beyond the phaseout under the authority of the Clean Air Act (CAA or the Act) and in accordance with the Montreal Protocol on Substances that Deplete the Ozone Layer (Protocol). In the "Rules and Regulations" section of today's Federal Register, we are authorizing these CSAs and critical uses as a direct final rule without prior proposal because we view this as a noncontroversial action and expect no adverse comment. We have explained our reasons for this authorization in the Preamble to the direct final rule. If we receive no adverse comment, we will not take further action on this proposed rule. If we receive adverse comment, we will withdraw the direct final rule and it will not take effect. We will address all public comments in the subsequent final rule based on this proposed rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

DATES: Written comments on the companion direct final rule must be received on or before September 29, 2005, or October 14, 2005 if a hearing is requested. Any party requesting a

public hearing must notify the contact person listed below by 5 p.m. Eastern Standard Time on September 9, 2005. If a hearing is requested it will be held September 14, 2005. Persons interested in attending a public hearing should consult with the contact person below regarding the location and time of the hearing.

ADDRESSES: Submit your comments, identified by Docket ID No. OAR-2004-0506, 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.
 - E-mail: mebr.allocation@epa.gov
- Fax: 202–343–2337 attn: Marta Montoro
- Mail: Air Docket, Environmental Protection Agency, Mailcode: 6102T, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In addition, please mail a copy of your comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and

Budget (OMB), Attn: Desk Officer for EPA, 725 17th St. NW., Washington, DC 20503.

• Hand Delivery: EPA Air Docket, EPA West 1301 Constitution Avenue, NW., Room B108, Mail Code 6102T, Washington, DC 20460. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. OAR-2004-0506. 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. 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 email 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 EDOCKET on-line or see the Federal

Register of May 31, 2002 (67 FR 38102).

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, i.e., 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 20460. 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: For further information about this proposed rule, contact Marta Montoro by telephone at (202) 343-9321, or by email at mebr.allocation@epa.gov, or by mail at Marta Montoro, U.S. Environmental Protection Agency, Stratospheric Protection Division, (6205]), 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Overnight or courier deliveries should be sent to 1310 L St. NW., Washington, DC 20005, attn: Marta Montoro. You may also visit the Ozone Depletion Web site of EPA's Stratospheric Protection Division at http://www.epa.gov/ozone/index.html for further information about EPA's Stratospheric Ozone Protection regulations, the science of ozone layer depletion, and other topics.

SUPPLEMENTARY INFORMATION: This document concerns the authorization of an additional 610,655 kilograms of methyl bromide for approved critical uses during 2005, through the allocation of CSAs. It also concerns additions to the list of approved critical uses for this control period. For further information, please see the information provided in the direct final action that is located in the "Rules and Regulations" section of this Federal Register publication.

This action concerns regulation of methyl bromide pursuant to the CAA as a class I, Group VI ozone-depleting substance. Under the CAA, methyl bromide production and consumption (defined as production plus imports minus exports) were phased out on January 1, 2005, apart from certain exemptions, including the critical use exemption, which is the subject of today's rule. In a final rule published December 23, 2004 (69 FR 76982), EPA established the framework for the critical use exemption; set forth a list of approved critical uses for 2005; and specified the amount of methyl bromide that could be supplied in 2005 from stocks and new production or import to meet approved critical uses. As part of that rule, EPA issued critical use allowances (CUAs) for new production and import and critical stock allowances (CSAs) for sale of methyl bromide stocks. In today's action, EPA is proposing to add uses of methyl bromide to the list of approved critical

uses and to issue additional CSAs for the 2005 control period. These actions are in accordance with Decision XVI/2 of the countries that have ratified the Montreal Protocol (the "Parties"), taken at their November 2004 meeting.

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 the regulatory action is "significant" and therefore subject to OMB review 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 has submitted this action to OMB for review. Changes made in response to OMB suggestions will be documented in the public record.

This proposed action will likely have a minor cost savings associated with its implementation, but the Agency did not conduct a formal analysis of savings given that such an analysis would have resulted in negligible savings. This proposed action represents the authorization only 2.5% of 1991 consumption baseline of methyl bromide to be made available for critical uses

B. Paperwork Reduction Act

The information collection requirements in this rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. The Information Collection Request (ICR) document prepared by EPA has been assigned EPA ICR number 1432.28 and OMB Control Number 2060–0170. This rule supplements the rule published in the **Federal Register** on December 23, 2004 (69 FR 76982). The information collection under these rules is authorized under Sections 603(b), 603(d) and 614(b) of the Clean Air Act (CAA).

The mandatory reporting requirements included in these rules are intended to:

(1) Satisfy U.S. obligations under the international treaty, The Montreal

Protocol on Substances that Deplete the Ozone Layer (Protocol), to report data under Article 7:

- (2) Fulfill statutory obligations under Section 603(b) of Title VI of the Clean Air Act Amendments of 1990 (CAA) for reporting and monitoring;
- (3) Provide information to report to Congress on the production, use and consumption of class I controlled substances as statutorily required in Section 603(d) of Title VI of the CAA.

In this rule, EPA is proposing to amend the Reporting and Recordkeeping Requirements in 40 CFR part 82 to require that entities report the amount of pre-phaseout methyl bromide inventory, held for sale or for transfer to another entity, to the Agency on an annual basis. Pre-phaseout refers to inventories of methyl bromide produced or imported prior to January 1, 2005. This additional requirement will allow EPA to track the drawdown of pre-phaseout inventories.

Collection activity	Number of respondents	Total number of responses	Hours per response	Total hours
Rule Familiarization	54 54 54	54 54 54	.5 .5 .5	27 27 27
Total Burden Hours		162		81

EPA informs respondents that they may assert claims of business confidentiality for any of the information they submit. Information claimed confidential will be treated in accordance with the procedures for handling information claimed as confidential under 40 CFR part 2, Subpart B, and will be disclosed only to the extent, and by means of the procedures, set forth in that subpart. If no claim of confidentiality is asserted when the information is received by EPA, it may be made available to the public without further notice to the respondents (40 CFR 2.203).

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; process and maintain information; disclose and provide 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

When this ICR is approved by OMB, the Agency will publish a technical amendment to 40 CFR part 9 in the **Federal Register** to display the OMB control number for the approved information collection requirements contained in these rules.

To obtain comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques. EPA has established a public docket for this rule, which includes this ICR, under Electronic Docket ID number OAR-2004-0506. Submit any comments related to the rule ICR for this proposed rule to EPA and OMB. See "Addresses" Section at the beginning of this notice for where to submit comments to EPA. Send comments to OMB at the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW., Washington DC 20503 attn: Desk Officer for EPA. Include the EPA ICR number 1432.28 in correspondence related to this ICR.

Since OMB is required to make a decision concerning the ICR between 30 and 60 days after August 30, 2005, a

comment to OMB is best assured of having its full effect if OMB receives it by September 29, 2005. The final rule will respond to any OMB or public concerns on the information collection requirements contained in this proposal.

C. Regulatory Flexibility Act (RFA)

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to noticeand-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 impacts of today's rule on small entities, small entity is defined as: (1) A small business that is identified by the North American Industry Classification System (NAICS) Code in the Table below; (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-forprofit enterprise which is independently owned and operated and is not dominant in its field.

Category	NAICS code	SIC code	NAICS small business size standard (in number of employees or millions of dollars)
Agricultural Production	1112—Vegetable and Melon farming	0171—Berry 0171—Berry Crops	\$0.75
	1114—Greenhouse, Nursery, and Floriculture Production.	0181—Ornamental Floriculture and Nursery products.	
Storage Uses	115114—Postharvest crop activities (except Cotton Ginning).	4221—Farm Product Warehousing and Storage	\$21.5
	493110—General Warehousing and Storage 493130—Farm product Warehousing Storage.	4225—General Warehousing and Storage.	

Agricultural producers of minor crops and entities that store agricultural commodities are categories of affected entities that contain small entities. This rule only affects entities that applied to EPA for a de-regulatory exemption. In most cases, EPA received aggregated requests for exemptions from industry consortia. On the exemption application, EPA asked consortia to describe the number and size distribution of entities their application covered. Based on the data provided, EPA estimates that there are 3,218 entities that petitioned EPA for an exemption. Since many applicants did not provide information on the distribution of sizes of entities covered in their applications, EPA estimated that between 1/4 to 1/3 of the entities may be small businesses based on the definition given above. In addition, other categories of affected entities do not contain small businesses based on the above description.

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. The small entities directly regulated by this proposed rule are primarily agricultural entities, producers, importers, and distributors of methyl bromide, as well as any entities holding inventory of methyl bromide.

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 proposed rule on small entities." (5 U.S.C. §§ 603–604). 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 a regulatory burden, or otherwise has a positive economic effect on all of the small entities subject to the rule. Since this rule will make additional methyl bromide available for approved critical uses after the phaseout date of January 1, 2005, this is a deregulatory action which will confer a benefit to users of methyl bromide. EPA believes the estimated de-regulatory value for users of methyl bromide is between \$20 million to \$30 million annually, as a result of the entire critical use exemption program over its projected duration. 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 impacts 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 by State, local and tribal governments, in the aggregate, or by 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 costeffective 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 of 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 under section 203 of UMRA a small government agency plan. 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.

EPA has determined that this rule does not contain a Federal mandate that may result in expenditures of \$100 million or more by State, local and tribal governments, in the aggregate, or by the private sector, in any one year. Today's proposed rule contains only one new mandate, which is the reporting requirement for the drawdown of prephaseout inventories. Today's amendment does not create a Federal mandate resulting in costs of \$100 million or more in any one year for State, local and tribal governments, in the aggregate, or for the private sector. Thus, today's proposed rule is not subject to the requirements of Sections 202 and 205 of the UMRA.

EPA has also determined that this proposed rule contains no regulatory requirements that might significantly or uniquely affect small governments; therefore, EPA is not required to develop a plan with regard to small governments under Section 203. Finally, because this proposal does not contain a significant intergovernmental mandate, the Agency is not required to develop a process to obtain input from elected State, local, and tribal officials under Section 204.

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 proposed rule is expected to primarily affect producers, suppliers, importers and exporters and users of methyl bromide. Thus, Executive Order 13132 does not apply to this proposed rule.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." This proposed rule does not have tribal implications, as specified in Executive Order 13175. Today's proposed rule does not significantly or uniquely affect the communities of Indian tribal governments. The proposed rule does not impose any enforceable duties on communities of Indian tribal governments. Thus, Executive Order 13175 does not apply to this proposed rule.

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

Executive Order 13045: "Protection of Children from Environmental Health Risks and Safety Risks" (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 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 that 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 does not establish an environmental standard intended to mitigate health or safety risks.

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

This rule is not a "significant energy action" as defined in Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355 (May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This rule does not pertain to any segment of the energy production economy nor does it regulate any manner of energy use. Further, we have concluded that this rule is not likely to have any adverse energy effects.

I. The National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 ("NTTAA"), Pub. L. 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 rulemaking does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

Dated: August 23, 2005.

Stephen L. Johnson,

Administrator.

[FR Doc. 05–17190 Filed 8–29–05; 8:45 am]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 410

[CMS-6024-P]

RIN 0938-AN10

Medicare Program; Prior Determination for Certain Items and Services

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: Section 938 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires the Secretary to establish a process for Medicare contractors to provide eligible participating physicians and beneficiaries with a determination of coverage relating to medical necessity for certain physicians' services before the services are furnished. This rule is intended to afford the physician and beneficiary the opportunity to know the financial liability for a service before expenses are incurred. This proposed rule would establish reasonable limits on physicians' services for which a prior determination of coverage may be requested and discusses generally our plans for establishing the procedures by which those determinations may be obtained.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on October 31, 2005.

ADDRESSES: In commenting, please refer to file code CMS-6024-P. Because of staff and resource limitations, we cannot accept comments by facsimile (fax) transmission.

You may submit comments in one of three ways (no duplicates, please):

- 1. Electronically. You may submit electronic comments to http://www.cms.hhs.gov/regulations/ecomments or to http://www.regulations.gov (attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word).
- 2. By mail. You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-6024-P, P.O. Box 8017, Baltimore, MD 21244-8017.

Please allow sufficient time for mailed comments to be received before the close of the comment period.