ENVIRONMENTAL PROTECTION AGENCY

[FRL–9442–9]

Protection of Stratospheric Ozone: Request for Applications for Essential Use Allowances for 2013 and 2014

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency is requesting applications for essential use allowances for calendar years 2013 and 2014. Essential use allowances provide exemptions from the phaseout of production and import of ozone-depleting substances. Essential use allowances must be authorized by the Parties to the Montreal Protocol on Substances that Deplete the Ozone Layer. The U.S. Government will use the applications received in response to this notice as the basis for its nomination of essential uses at the 24th Meeting of the Parties to the Protocol, to be held in 2012.

DATES: Applications for essential use allowances must be submitted to EPA no later than September 20, 2011 in order for the U.S. Government to complete its review and to submit nominations to the United Nations Environment Programme and the Protocol Parties in a timely manner.

ADDRESSES: Send application materials to: Jeremy Arling, Stratospheric Protection Division (6205J), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. For applications sent via courier service, use the following direct mailing address: 1310 L Street, NW., Washington, DC 20005, Room 1047E.

Confidentiality: Application materials that are confidential should be submitted under separate cover and be clearly identified as ''trade secret,'' ''proprietary,'' or ''company confidential.'' Information covered by a claim of business confidentiality 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. Please note that data will be presented in aggregate form by the United States as part of the nomination to the Parties. If no claim of confidentiality accompanies the information when it is received by EPA, the information may be made available to the public by EPA without further notice to the company (40 CFR 2.203).

FOR FURTHER INFORMATION CONTACT: Jeremy Arling at the above address, or by telephone at (202) 343–9055, by fax at (202) 343–2338, or by e-mail at *arling.jeremy@epa.gov.* Information about essential uses may be obtained from EPA's stratospheric protection Web site at *http://www.epa.gov/ozone/title6/exemptions/essential.html.*

SUPPLEMENTARY INFORMATION:

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I. Background on the Essential Use Nomination Process

The Parties to the Protocol agreed during the Fourth Meeting in Copenhagen on November 23–25, 1992, that non-Article 5 Parties (developed countries) would phase out the production and consumption of halons by January 1, 1994, and the production and consumption of other class I substances (under 40 CFR part 82, subpart A), except methyl bromide, by January 1, 1996. The Parties also reached decisions and adopted resolutions on a variety of other matters, including the criteria to be used for allowing ''essential use'' exemptions from the phaseout of production and import of controlled substances. Decision IV/25 of the Fourth Meeting of the Parties details the specific criteria and review process for granting essential use exemptions.

Decision IV/25, paragraph 1(a), states 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.'' In addition, the Parties agreed ''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 the existing stocks of banked or recycled controlled substances * * *'' Decision XII/2 of the Twelfth Meeting of the Parties states that any CFC metered dose inhaler (MDI) product approved after December 31, 2000, is nonessential unless the product meets the criteria in Decision IV/25, paragraph 1(a).

The first step in obtaining essential use allowances is for the user to consider whether the use of the controlled substance meets the criteria of Decision IV/25. If the essential use request is for an MDI product, the user should also consider whether the product meets the criteria of Decision XII/2. In addition, the user should consult recent and ongoing rulemakings by the Food and Drug Administration (FDA) concerning the essential use determination of various MDI moieties. In particular, users should consider FDA's November 19, 2008, final rulemaking that removes the essential use designation for epinephrine used in MDIs as of December 31, 2011 (73 FR 69532). Users should also consider FDA's April 14, 2010, rulemaking that removes the essential use designations for flunisolide, triamcinolone, metaproterenol, pirbuterol, albuterol and ipratropium in combination, cromolyn, and nedocromil used in MDIs at various dates depending upon the inhaler (75 FR 19213).

Users requesting essential use allowances for calendar years 2013 and 2014 should send a completed application to EPA on the candidate use. The application should include information that U.S. Government agencies and the Parties to the Protocol can use to evaluate the candidate use according to the criteria in the Decisions described above.

Upon receipt of applications, EPA reviews the information and works with other interested Federal agencies to determine whether the candidate use meets the essential use criteria and warrants nomination by the United States for an exemption. In the case of multiple exemption requests for a single use, such as for MDIs, EPA aggregates exemption requests received from individual entities into a single U.S. request. An important part of the EPA review is to ensure that the aggregate request for a particular future year adequately reflects the total market need for CFC MDIs and expected availability of CFC substitutes by that point in time. If the sum of individual requests does not account for such factors, the U.S. Government may adjust the aggregate request to better reflect true market needs.

Nominations submitted by the United States and other Parties are forwarded by the United Nations Ozone Secretariat to the Montreal Protocol's Technical and Economic Assessment Panel (TEAP) and its Medical Technical Options Committee (MTOC), which reviews the submissions and makes

recommendations to the Parties for essential use exemptions. The Parties then consider those recommendations at their annual meeting before making a final decision. If the Parties declare a specified use of a controlled substance as essential, and authorize an exemption from the Protocol's production and consumption phaseout, EPA may propose regulatory changes to reflect the decisions by the Parties, but only to the extent such action is consistent with the Clean Air Act. Applicants should be aware that essential use exemptions granted to the United States under the Protocol in recent years have been limited to CFCs for MDIs to treat asthma and chronic obstructive pulmonary disease. Applicants should also be aware that the Parties last authorized an essential use exemption for United States in 2008 for the 2010 calendar year.

The Parties review nominations for essential use exemptions for the following year and subsequent years. This means that, if nominated, applications submitted in response to today's notice for an exemption in 2013 and 2014 will be considered by the Parties in 2012 for final action. The quantities of controlled substances that are requested in response to this notice, if approved by the Parties to the Montreal Protocol, will then be allocated as essential use allowances to the specific U.S. companies through notice-and-comment rulemaking, to the extent that such allocations are consistent with the Clean Air Act.

II. Information Required for Essential Use Applications for Production or Import of Class I Substances in 2013 and 2014

Through this action, EPA requests applications for essential use exemptions for all class I substances, except methyl bromide, for calendar years 2013 and 2014. This notice is the last opportunity to submit new or revised applications for 2013. This notice is also the first opportunity to submit requests for 2014. Companies will have an opportunity in 2012 to submit new, supplemental, or amended applications for 2014. All requests for exemptions submitted to EPA should present information as requested in the current version of the TEAP *Handbook on Essential Use Nominations,* which was updated in 2009. The handbook is available electronically on the Web at *http://ozone.unep.org/teap/Reports/TEAP_Reports/EUN-Handbook2009.pdf.*

In brief, the TEAP Handbook states that applicants should present information on:

- Role of use in society;
- Alternatives to use;
- Steps to minimize use;
- Recycling and stockpiling;
- Quantity of controlled substances requested; and
- Approval date and indications (for MDIs).

In addition, entities should address the following points to ensure that their applications are clear and complete. First, entities that request CFCs for multiple companies should clearly state the amount of CFCs requested for each company. Second, all essential use applications for CFCs should provide a breakdown of the quantity of CFCs necessary for each MDI product to be produced. This detailed breakdown will allow EPA and FDA to make informed decisions regarding the amount of CFCs to be nominated by the U.S. Government for the years 2013 and 2014. Third, all new drug application (NDA) holders for CFC MDI products produced in the United States should submit a complete application for essential use allowances either on their own or in conjunction with their contract filler. In the case where a contract filler produces a portion of an NDA holder's CFC MDIs, the contract filler and the NDA holder should determine the total amount of CFCs necessary to produce the NDA holder's entire product line of CFC MDIs. The NDA holder should provide an estimate of how the CFCs would be split between the contract filler and the NDA holder in the allocation year. This estimate will be used only as a basis for determining the nomination amount, and may be adjusted prior to allocation of essential use allowances. Since the U.S. Government does not forward incomplete or inadequate nominations to the Ozone Secretariat, it is important for applicants to provide all information requested in the Handbook, including comprehensive information pertaining to the research and development of alternative CFC MDI products per Decision VIII/10, para. 1 as specified in the Supplement to Nomination Request (pg. 46).

Finally, consistent with Decision XIX/13 taken in September 2007 at the 19th Meeting of the Parties, when requesting essential use CFCs for MDIs, applicants should provide the following information: (1) The company's commitment to the reformulation of the concerned products; (2) the timetable in which each reformulation process may be completed; and (3) evidence that the company is diligently seeking approval of any CFC-free alternative(s) in its domestic and export markets and transitioning those markets away from its CFC products.

The accounting framework matrix in the Handbook (Table IV) titled ''Reporting Accounting Framework for Essential Uses Other Than Laboratory and Analytical Applications'' requests data for the year 2011 on the amount of ODS exempted for an essential use, the amount acquired by production, the amount acquired by import and the country(s) of manufacture, the amount on hand at the start of the year, the amount available for use in 2011, the amount used for the essential use, the quantity contained in exported products, the amount destroyed, and the amount on hand at the end of 2011. Because all data necessary for applicants to complete Table IV will not be available until after the control period ends on December 31, 2011, companies should not include this chart with their essential use applications in response to this notice. Instead, companies should report their data as required by 40 CFR 82.13(u)(2) in Section 5 of the report titled ''Essential Use Allowance Holders and Laboratory Supplier Quarterly Report and Essential Use Allowance Holder Annual Report.'' This form may be found on EPA's Web site at *http://www.epa.gov/ozone/record/downloads/EssentialUse_ClassI.doc.* EPA will then compile each company's responses and complete the U.S. Accounting Framework for Essential Uses for submission to the Parties to the Montreal Protocol by the end of January 2012. EPA may also request additional information from companies to support the U.S. nomination using its information gathering authority under section 114 of the Act.

EPA anticipates that the Parties' review of MDI essential use requests will focus extensively on the United States' progress in phasing out CFC MDIs, including education programs to inform patients and health care providers of the CFC phaseout and the transition to alternatives. Accordingly, applicants are strongly advised to present detailed information on these educational programs, including the scope and cost of such efforts and the medical and patient organizations involved in the work. In addition, EPA expects that Parties will be interested in research and development activities being undertaken by MDI manufacturers to develop and transition to alternative CFC-free MDI products. To this end, applicants are encouraged to provide detailed information on these efforts. Applicants should submit their exemption requests to EPA as noted in the **ADDRESSES** section above.

The Office of Management and Budget (OMB) has approved the information

collection requirements contained in this notice under the provisions of the *Paperwork Reduction Act,* 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2060–0170.

Dated: July 18, 2011.

Elizabeth Craig,

Acting Director, Office of Atmospheric Programs.

[FR Doc. 2011–18573 Filed 7–21–11; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Submitted for Review and Approval to the Office of Management and Budget (OMB), Comments Requested

July 15, 2011.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, 44 U.S.C. 3501—3520. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and (e) ways to further reduce the information collection burden for small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a currently valid OMB control number.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before August 22, 2011. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, Office of Management and Budget, via fax at 202–395–5167 or via the Internet at *Nicholas_A._Fraser@omb.eop.gov* and to the Federal Communications Commission via e-mail to *PRA@fcc.gov.* To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the Web page, (2) look for the section of the Web page called ''Currently Under Review'', (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, and (6) when the list of FCC ICRs currently under review appears, look for the title of this ICR (or its OMB Control Number, if there is one) and then click on the ICR Reference Number to view detailed information about this ICR.

FOR FURTHER INFORMATION CONTACT: Leslie F. Smith, Office of Managing Director, (202) 418–0217. For additional information or copies of the information collection(s), contact Leslie F. Smith via e-mail at *PRA@fcc.gov* or call 202–418–0217.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0411.

Title: Procedures for Formal Complaints.

Form Number: FCC Form 485.

Type of Review: Revision of a currently approved collection.

Respondents: 20.

Number of Responses: 301.

Estimated Time per Response: 4.5 hours (average).

Frequency of Response: Recordkeeping; on occasion reporting requirements; and third party disclosure requirements.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 151, 154(i), 154(j), 206, 207, 208, 209, 301, 303, 304, 309, 316, 332, and 1302.

Total Annual Burden: 1,349 hours.

Total Annual Cost: $1,847, 600.

Privacy Act Impact Assessment: As noted on OMB Form 83–I, the information collection requirements affect individuals or households. As required by the Privacy Act of 1974, as amended, 5 U.S.C. 552a, and OMB Memorandum m–03–22 (September 22, 2003), the FCC is complying with these requirements by: (1) Having published a system of records notice (SORN) in the **Federal Register** on December 14, 2010 (75 FR 77872) for a system of records, FCC/EB–5, ''Enforcement Bureau Activity Tracking System (EBATS).'' The SORN became effective on January 24, 2001; and (2) consolidating and updating Privacy Impact Assessment (PIA). Together these two documents will cover the collection, maintenance, use, and disposal of all personally identifiable information (PII) that may be submitted as part of any formal complaint(s) that are filed.

Nature and Extent of Confidentiality: 47 CFR 1.731 provides for confidential treatment of materials disclosed or exchanged during the course of formal complaint proceedings when those materials have been identified by the disclosing party as proprietary or confidential. In the rare case in which a producing party believes that section 1.731 will not provide adequate protection for its asserted confidential material, it may request either that the opposing party consent to greater protection, or that the staff supervising the proceeding order greater protection.

Needs and Uses: 47 CFR 1.731 provides for confidential treatment of materials disclosed or exchanged during the course of formal complaint proceedings when those materials have been identified by the disclosing party as proprietary or confidential. In the rare case in which a producing party believes that section 1.731 will not provide adequate protection for its asserted confidential material, it may request either that the opposing party consent to greater protection, or that the staff supervising the proceeding order greater protection.

Needs and Uses: The Commission is seeking a revision of collection 3060–0411, which relates to the filing of formal complaints with the Federal Communications Commission. The revision is necessitated by the adoption of a new data roaming rule (47 CFR 20.12(e)) contained in the *Second Report and Order,* Reexamination of Roaming Obligations of Commercial Mobile Radio Service Providers and Other Providers of Mobile Data Services, WT Docket No. 05–265, FCC 11–52, that was adopted on April 7, 2011. The new data roaming rule requires commercial mobile data service providers to offer data roaming arrangements to other such providers on commercially reasonable terms and conditions, subject to certain limitations.

To resolve complaints between providers regarding compliance with data roaming obligations, the rule adopts by reference the procedures already in place for resolving formal complaints against common carriers,