Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 2

[Docket No. 2006N–0454]

RIN 0910–AF93

Use of Ozone-Depleting Substances; Removal of Essential-Use Designations; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule, extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to September 10, 2007, the comment period for the proposed rule published in the **Federal Register** of June 11, 2007 (72 FR 32030). The proposed rule would amend FDA's regulation on the use of ozone-depleting substances (ODSs) in self-pressurized containers to remove the essential-use designations for oral pressurized metered-dose inhalers (MDIs) containing flunisolide, triamcinolone, metaproterenol, pirbuterol, albuterol and ipratropium in combination, cromolyn, and nedocromil. FDA is taking this action in response to a request for an extension.

DATES: Submit written or electronic comments by September 10, 2007.

ADDRESSES: You may submit comments, identified by Docket No. 2006N–0454, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted directly to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and docket number and Regulatory Information Number (RIN) for this rulemaking. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents, comments, a transcript of, and material submitted for, the Pulmonary-Allergy Advisory Committee meeting held on June 10, 2005, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Wayne H. Mitchell or Martha Nguyen, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2007 (72 FR 32030), we published a proposed rule (the proposed rule) to amend FDA's regulation on the use of ozone-depleting substances (ODSs) in self-pressurized containers (21 CFR 2.125) to remove the essential-use designations for MDIs containing flunisolide, triamcinolone, metaproterenol, pirbuterol, albuterol and ipratropium in combination, cromolyn, and nedocromil. In the **Federal Register** of July 9, 2007 (72 FR 37137), we published a notice of an open public meeting (meeting notice) to be held on August 2, 2007. In the proposed rule and meeting notice, we invited interested persons to comment on the proposed rule by August 10, 2007.

The agency has received a request for a 90-day extension of the comment period from Graceway Pharmaceuticals, LLC (Graceway) (Docket No. 2006N–0454/EXT1). Graceway subsequently supplemented this request with a request dated July 17, 2007, to reschedule the August 2, 2007, public meeting on the proposed rule. Graceway holds the new drug application (NDA) for MAXAIR AUTOHALER, a pirbuterol MDI that uses an ODS as a propellant. The proposed rule would remove from the market pirbuterol MDIs that contain an ODS.

Graceway requested that FDA extend the comment period by 90 days because the proposal presents complex medical, scientific, and economic issues and the existing comment period does not allow sufficient time to develop a meaningful or thoughtful response to the request for comments.

FDA has considered the request and is extending the comment period on the proposed rule for 30 days, until September 10, 2007. The agency believes this extension will allow adequate time for interested persons to submit comments while still permitting FDA and the U.S. Government to meet their obligations under the Clean Air Act (42 U.S.C. 7401 *et seq.*) and the Montreal Protocol on Substances that Deplete the Ozone Layer (Montreal Protocol) (September 16, 1987, 26 I.L.M. 1541 (1987)), available at *http://www.unep.org/ozone/pdfs/Montreal-Protocol2000.pdf*.[1] This rulemaking necessarily relates to other actions taken or to be taken by the U.S. Government, including requesting essential-use exemptions from the Parties to the Montreal Protocol for quantities of ODSs for use in MDIs and allocation of the ODSs to U.S. manufacturers for use in MDIs under section 604(d) of the Clean Air Act (42 U.S.C. 7671c). Delays in

[1] FDA has verified all Web site addresses cited in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document has published in the **Federal Register**.

finalizing this proposed rule potentially could delay or prevent the U.S. Government from taking actions to ensure a smooth transition to inhaled drug products for the treatment of asthma and chronic obstructive pulmonary disease that do not contain ODSs. We note that interested persons have had ample notice that FDA was considering removing the essential-use designation for pirbuterol and the six other drugs that are the subject of this rulemaking, including the following:

- This issue was first considered at the July 14, 2005, meeting of the Pulmonary-Allergy Advisory Committee (see 70 FR 24605, May 10, 2005). The trade press reported on this meeting; and minutes and a transcript of the meeting were placed on the Internet.[2]
- At the 17th Meeting of the Parties to Montreal Protocol (Dakar, Senegal, December 12 through 16, 2005), the Parties decided that developed countries should provide a date to the Ozone Secretariat before the 18th meeting of the Parties (New Delhi, October 30 through November 3, 2006), by which time a regulation or regulations will have been proposed to determine whether MDIs, other than those that have albuterol as the only active ingredient, are nonessential.[3] The U.S. Government provided information to the Ozone Secretariat that a proposed rule that would eliminate the essential-use designation of pirbuterol and the six other drugs that are the subject of the proposed rule should publish by the end of May 2007.
- We also announced our intention to publish a proposed rule by the end of May 2007 that would eliminate the essential-use designation of pirbuterol and the six other drugs that are the subject of the proposed rule in the Unified Agendas[4] published in the **Federal Register** on December 11, 2006 (71 FR 73195 at 73223), and April 30, 2007 (72 FR 22489 at 22156).

Because interested persons have had ample notice of this rulemaking dating back at least to May 2005, we do not intend to grant further requests for extension of the comment period on the proposed rule.

As discussed in the previous paragraphs, FDA believes this extension will allow adequate time for interested persons to submit comments on the proposed rule, and that rescheduling the public meeting was unnecessary. The deadline for registration passed soon after the request to reschedule the meeting was made and interested persons had already made travel and other arrangements to participate on the scheduled date. Anyone who was unable to participate in the meeting still has the opportunity to submit written comments for an additional 30 days, as outlined in this notice.

II. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the proposed rule (see **DATES**). Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 1, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7–15372 Filed 8–6–07; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

49 CFR Part 622

Federal Highway Administration

23 CFR Part 771

[Docket No. FTA–2006–26604]

RIN 2132–AA87

Environmental Impact and Related Procedures

AGENCIES: Federal Transit Administration (FTA), Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: This notice of proposed rulemaking (NPRM) provides interested parties with the opportunity to comment on proposed changes to the joint FTA/FHWA procedures that implement the National Environmental Policy Act (NEPA). The revisions are prompted by enactment of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU), which prescribes additional requirements for environmental review and project decisionmaking that are not appropriately reflected in the existing joint NEPA procedures. Pursuant to provisions of SAFETEA–LU, this NPRM proposes to add new categorical exclusions (CEs) from the NEPA process. This NPRM also proposes other minor changes to the joint procedures in order to improve the description of the procedures or to provide clarification with respect to the interpretation of certain provisions. The FTA and the FHWA seek comments on the proposals contained in this notice.

DATES: Comments must be received by October 9, 2007.

ADDRESSES: *Written Comments:* Submit written comments to: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Ave. SE., Washington, DC 20590.

Comments. You may submit comments identified by the docket number (FTA–2006–26604) by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Web site: http://dms.dot.gov.* Follow the instructions for submitting comments on the DOT electronic docket site.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management System, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Ave. SE., Washington, DC 20590.
- *Hand Delivery:* To the Docket Management System; U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Ave. SE., Washington, DC 20590 between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

Instructions: All submissions must include the agency name and docket number or Regulatory Identification Number (RIN) of this notice. Note that all comments received will be posted without change to *http://dms.dot.gov* including any personal information provided. Please see the Privacy Act heading under **SUPPLEMENTARY INFORMATION.**

Docket: For access to the docket to read background documents or comments received, go to *http://dms.dot.gov* at any time or to the Docket Management System. (See **ADDRESSES.**)

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[2] ''CFC-Only Asthma Drugs Likely to Lose 'Essential Use' Designation,'' *The Pink Sheet*, July 18, 2005, p. 15; minutes of the meeting and a transcript of the meeting are available at *http://www.fda.gov/ohrms/dockets/* (select ''Advisory Committee Materials,'' then ''2005,'' then ''Pulmonary-Allergy Drugs Advisory Committee'').

[3] For more information, see the discussion in the proposed rule (72 FR 32030 at 32031 and 32032).

[4] The Unified Agenda (also known as the Semiannual Regulatory Agenda), published twice a year in the **Federal Register**, summarizes the rules and proposed rules that each Federal agency expects to issue during the next 6 months.