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; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to solicit comments on a proposed rule that would amend FDA’s regulation on the use of ozone-depleting substances (ODSs) in self-pressurized containers to remove essential-use designations for certain oral pressurized metered-dose inhalers (MDIs). In the Federal Register of June 11, 2007 (72 FR 32030), the agency proposed to remove the essential use designation for MDIs containing flunisolide, triamcinolone, metaproterenol, pirbuterol, albuterol and ipratropium in combination, cromolyn, and nedocromil. Information from the public meeting, which is required by agency regulations, will be considered in finalizing the rulemaking.

DATES: The public meeting will be held on August 2, 2007, from 9 a.m. to 3:30 p.m. Submit written or electronic comments for consideration at the meeting and requests to speak at the meeting by July 25, 2007. Register to attend the meeting by July 25, 2007. Submit written or electronic comments on the proposed rule and this notice by August 10, 2007.
ADDRESSES: The public meeting will be held at FDA, Center for Drug Evaluation and Research Advisory Committee Conference Room, 5630 Fishers Lane, rm. 1066, Rockville, MD 20852. You may submit comments, identified by Docket No. 2006N–0454 and RIN number 0910–AF93, by any of the following methods:

Electronic Submissions
Submit electronic comments in the following ways:


Written Submissions
Submit written submissions in the following ways:

- 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 the Electronic Submissions portion of this paragraph.

Instructions: All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) 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 the proposed rule, background documents, or comments received, go to http://www.fda.gov/ohrms/dockets/default.htm and insert the docket number(s) 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: Terry Martin, Center for Drug Evaluation and Research (HFD–6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5376, e-mail: theresa.martin@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Clean Air Act, FDA, in consultation with the EPA, is required to determine whether an FDA-regulated product that releases an ODS is an essential use of the ODS. In the Federal Register of June 11, 2007 (72 FR 32030) (the proposed rule), we proposed to amend our regulation on the use of ODSs in self-pressurized containers to remove the essential-use designations of MDIs containing flunisolide, triamcinolone, metaproterenol, pirbuterol, albuterol and ipratropium in combination, cromolyn, and nedocromil. You may find copies of the proposed rule on the Division of Dockets Management Web site (see ADDRESSES) and the GPO Access Web site at http://www.gpoaccess.gov/fr/index.html. If the applicable essential-use designations are all removed, flunisolide, triamcinolone, metaproterenol, pirbuterol, albuterol and
ipratropium in combination, cromolyn, and nedocromil MDIs containing an ODS could not be marketed after the effective date of the final rule removing the essential-use designations.

In proposing to remove the essential-use designation for the seven drugs that are the subject of the proposed rule, we applied the criterion for removing an essential-use designation in § 2.125(g)(2) (21 CFR 2.125(g)(2)) to each drug. Under § 2.125(g)(2), an essential-use designation can be removed if it no longer meets the criteria specified in § 2.125(f) for adding a new essential use. The criteria in § 2.125(f) provides that * * * Substantial technical barriers exist to formulating the product without ODSs; the product will provide an unavailable important public health benefit; and use of the product does not release cumulatively significant amounts of ODSs into the atmosphere or the release is warranted in view of the unavailable important public health benefit. * *

We proposed that the removal of the essential-use designations be made effective on December 31, 2009. In the proposed rule we said that depending on the data presented to us in the course of the rulemaking, we may determine that it is appropriate to have different effective dates for removing the essential-use designation for different drugs (72 FR 32030 at 32034).

The provisions in § 2.125(g)(2) that provide the procedures and criteria being used in this rulemaking require that a public meeting be held before an essential use may be removed. This notice announces the meeting that will be held to fulfill that requirement, which will also better inform the decisions we will be making during the rulemaking.
II. Issues and Questions for Discussion and Comment

If you are going to speak at the meeting or submit a written comment, you may address any issue raised in the proposed rule or on any other issue that is relevant to our decision on the proposed rule. You may wish to discuss how the criteria described in section I of this document apply to MDIs containing flunisolide, triamcinolone, metaproterenol, pirbuterol, albuterol and ipratropium in combination, cromolyn, and nedocromil. You may also wish to discuss whether different effective dates are appropriate for different drugs (72 FR 32030 at 32034). We invite discussion of issues on which we specifically asked for comments in the proposed rule, including the following:

- Do the other available therapies provide adequate alternatives for each of the seven drugs from a public health perspective? (72 FR 32030 at 32034)
- Will production of albuterol HFA\(^1\) MDIs be able to meet any increased demand caused by this rulemaking? (72 FR 32030 at 32035)
- Are portable nebulizers suitable therapeutic alternatives for cromolyn MDIs and nedocromil MDIs, and will use of portable nebulizers be important in meeting the needs of patients who are currently using cromolyn MDIs and nedocromil MDIs? (72 FR 32030 at 32037 and 32038)
- Does use of a single MDI containing albuterol and ipratropium in combination provide for better patient outcomes (e.g., fewer exacerbations or increased quality of life) compared to concomitant use of separate albuterol and ipratropium MDIs, and, if these improvements are shown to exist, should they be considered important public health benefits? (72 FR 32030 at 32039)

We consulted with FDA’s Pulmonary and Allergy Drugs Advisory Committee (PADAC) at their July 14, 2005, meeting on the essential-use status

\(^1\)“HFA” is used in the pharmaceutical industry, and is used here, to refer to the hydrofluoroalkane HFA–134a, a non-ozone-depleting propellant.
of MDIs containing flunisolide, triamcinolone, metaproterenol, pirbuterol, albuterol and ipratropium in combination, cromolyn, and nedocromil. During the meeting, several PADAC members expressed opinions that MDIs containing cromolyn and MDIs containing albuterol and ipratropium in combination provide important public health benefits. You may wish to read the transcript of the PADAC meeting (available on the Division of Dockets Management Web site (see ADDRESSES)) or the summaries of the discussions at the PADAC meeting in the proposed rule and comment on our tentative findings that MDIs containing cromolyn and MDIs containing albuterol and ipratropium in combination do not provide important public health benefits (72 FR 32030 at 32037 to 32039).

III. Registration, Agenda, and Transcript

There is no fee to register for the meeting, but registration is required and space is limited. Interested parties are therefore encouraged to register early. Limited visitor parking is available for a fee, and the Twinbrook Metro Stop is within walking distance of the meeting site. Early arrival is encouraged, as there will be security screening. You will be asked for government-issued picture identification by the security officers. If you need special accommodations due to a disability, please include this information when registering.

Registration for General Attendees: Registration is required to attend the public meeting. If you wish to attend the meeting, you must register by July 25, 2007, via e-mail to: theresa.martin@fda.hhs.gov. Please indicate “Essential-Use Designation of Seven Drugs” in the SUBJECT line and provide complete contact information for each attendee (including name, title, affiliation, e-mail
address, and phone number(s)). Upon receipt and review for adequacy of information, an e-mail will be sent to confirm registration.

Registration for Speaking Attendees: If you wish to speak at the meeting, you must register by July 25, 2007, via e-mail to: theresa.martin@fda.hhs.gov. Please indicate “Speaker- Essential Use-Designation of Seven Drugs” in the SUBJECT line. When registering, speakers must provide the following information: (1) The drug product, topic, or issue to be addressed; (2) the speaker’s name, title, company or organization, address, phone number, and e-mail address; and (3) the approximate length of time requested to speak. We encourage consolidation of like-minded presentations to enable a broad range of views to be presented.

Agenda and Transcript: The agenda for the public meeting will be available on FDA’s Center for Drug Evaluation and Research (CDER) Web site at: http://www.fda.gov/cder/meeting/ozone2007.htm. After the meeting, the agenda, presentations, and transcript will be placed on file in the Division of Dockets Management under Docket No. 2006N–0454 and on CDER’s Web site identified previously.

Copies of the transcript may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 20 working days after the meeting at a cost of 10 cents per page, or on compact disc at a cost of $14.25 each. You may also examine the transcript at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and on the Internet at http://www.fda.gov/ohrms/dockets/default.htm.
IV. Comments

Regardless of your attendance at the meeting, you may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments related to the proposed rule by August 10, 2007. All relevant data and information should be submitted with the written comments. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one copy. Comments are to be
identified with Docket No. 2006N-0454. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 2, 2007.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 07–???? Filed ??–??–07; 8:45 am]

BILLING CODE 4160–01–S

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL