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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 2

Display Date 11-5-07 4:01 pm
Publication Date 11-8-07
Certifier A. Corbin

[Docket No. 2007N-0262]

RIN 0910-AF92

Use of Ozone-Depleting Substances; Removal of Essential-Use Designation (Epinephrine); Public Meeting; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; notice of public meeting and extension of comment period.

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 the essential-use designation for oral pressurized metered-dose inhalers (MDIs) containing epinephrine. The proposed rule was published in the **Federal Register** of September 20, 2007 (72 FR 53711). Information from the public meeting, which is required by agency regulations, will be considered in finalizing the rulemaking. In addition, the comment period on the proposed rule is being extended to December 19, 2007, to accommodate the meeting and to provide a short period after the meeting to receive additional comments.

DATES: The comment period for the September 20, 2007 (72 FR 53711) proposed rule is being extended to December 19, 2007. The public meeting will be held on December 5, 2007, from 9 a.m. to 3:30 p.m. Submit written

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or electronic comments for consideration at the meeting and requests to speak at the meeting by November 23, 2007. Register to attend the meeting by November 23, 2007. Submit written or electronic comments on the proposed rule and this document by December 19, 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. 2007N-0262 and RIN number RIN 0910-AF92, 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 No(s). 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 “Request for 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 2007N–0262, 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: Rose Cunningham, Center for Drug Evaluation and Research (HFD–6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5383, E-mail: CDEREXSEC@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Clean Air Act, FDA, in consultation with the Environmental Protection Agency, 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 September 20, 2007 (72 FR 53711) (the proposed rule), we proposed to amend our regulation on the use of ODSs in self-pressurized containers to remove the essential-use designation of MDIs containing epinephrine. 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 essential-use designation is removed, epinephrine MDIs containing an ODS could not be marketed after the effective date of the final rule removing the essential-use designation.

In proposing to remove the essential-use designation for epinephrine, we applied the criterion for removing an essential-use designation in § 2.125(g)(2) (21 CFR 2.125(g)(2)). 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)(1) are: “(i) Substantial technical barriers exist to formulating the product without ODSs; (ii) The product will provide an unavailable important public health benefit; and (iii) 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 designation for epinephrine be made effective on December 31, 2010. Depending on the data presented to us in the course of the rulemaking, we may determine that it is appropriate to have a different effective date than the one we proposed.

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 document 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 epinephrine. You may wish to discuss how the fact that epinephrine MDIs are the most widely used over-the-counter (OTC) treatment for the symptoms of asthma should affect our decision. You may also wish to discuss whether a different effective date is appropriate. We invite discussion of issues on which we specifically asked for comments in the proposed rule, including the following.

- Will production of albuterol HFA¹ MDIs (a primary therapeutic alternative to OTC epinephrine MDIs) be able to meet any increased demand caused by this rulemaking? (72 FR 53711 at 53716)
- Will inhaled epinephrine become available in a non-ODS formulation and when can a non-ODS inhaled-epinephrine product be reasonably expected to enter the market? (72 FR 53711 at 53716)
- Should the availability of an inhaled-epinephrine OTC drug product that does not contain ODSs affect whether we publish a final rule or the effective date of any such rule? (72 FR 53711 at 53716)
- What efforts are currently being made to develop non-ODS inhaled-epinephrine drug products that would be suitable for OTC sale? (72 FR 53711 at 53718)
- What are the impediments to developing non-ODS inhaled-epinephrine drug products that would be suitable for OTC sale? (72 FR 53711 at 53718)
- How many people who face barriers to health care purchase epinephrine MDIs because of those barriers to health care? (72 FR 53711 at 53720)

¹“HFA” is used in the pharmaceutical industry, and is used here, to refer to the hydrofluoralkane HFA-134a, a non-ozone-depleting propellant.

- Will programs providing free or low-cost drugs reduce any adverse impact on the public health caused by the removal of OTC epinephrine MDIs from the market? (72 FR 53711 at 53722)
- Do risks of self-treatment of asthma outweigh the public health benefits that OTC epinephrine MDIs may provide? (72 FR 53711 at 53722)
- What are the expected costs and public health effects to individuals with asthma if OTC epinephrine MDIs were removed from the market without a similar product being available OTC? (72 FR 53711 at 53722)

We consulted with FDA's Nonprescription Drugs Advisory Committee and Pulmonary and Allergy Drugs Advisory Committee at a joint meeting held on January 24, 2006, to discuss the essential-use status of MDIs containing epinephrine. During the meeting, several committee members expressed opinions that MDIs containing epinephrine provide important public health benefits to individuals with asthma who face barriers to health care and cannot obtain prescription drugs. You may wish to read the transcript of the joint meeting (available on the Division of Dockets Management Web site (see **ADDRESSES**)) or the summaries of the discussions at the meeting in the proposed rule (72 FR 53711 at 53716 to 53724).

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 November 23, 2007, via e-mail to: CDEREXSEC@fda.hhs.gov. Please indicate “Essential-Use Designation of Epinephrine” 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 November 23, 2007, via e-mail to: CDEREXSEC@fda.hhs.gov. Please indicate “Speaker--Essential Use-Designation of Epinephrine” in the SUBJECT line. When registering, speakers must provide the following information: (1) The 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. 2007N-0262 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. 6-30, 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. Extension of the Comment Period for the Proposed Rule

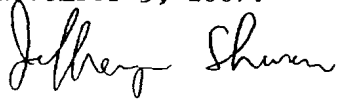
FDA is extending the comment period for the proposed rule to December 19, 2007. We believe that extending the comment period is reasonable to accommodate the public meeting and to provide a short period after the meeting to receive additional comments.

V. Request for 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 (see **DATES**). 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. 2007N-0262. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 11/5/07

November 5, 2007.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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

BILLING CODE 4160-01-S

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