

Reauthorization Act (CHIPRA). The initial core measure set is required to be posted for public comment by January 1, 2010. CHIPRA reauthorized the Child Health Insurance Program (CHIP) originally established in 1997, and in Title IV of the law, added a number of new provisions designed to improve health care quality and outcomes for children. AHRQ is working closely with the Centers for Medicare and Medicaid Services (CMS) in implementing these provisions. For more information about AHRQ's role in carrying out the quality provisions of CHIPRA, see <http://www.ahrq.gov/chip/chipraact.htm>.

## II. Agenda

On Thursday, September 17, 2009, the Subcommittee meeting will convene at 8 a.m., with the call to order by the Subcommittee Co-Chairs. The meeting will review results of the second stage of the Delphi Process of scoring measures for validity, feasibility, and importance, and proceed to select an initial core set of children's healthcare quality measures to recommend to the AHRQ National Advisory Committee (NAC). This process was started in the first subcommittee meeting, held July 22–23, 2009.

A more specific proposed agenda will be available before the meeting from Padmini Jagadish, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, Maryland 20850, (301) 427–1927, e-mail address [Padmini.Jagadish@ahrq.hhs.gov](mailto:Padmini.Jagadish@ahrq.hhs.gov). The final agenda, including the time for public comment during the meeting, will be available on the AHRQ Web site at <http://www.ahrq.gov/chip/chipraact.htm> no later than September 10, 2009. This AHRQ Web site links to an email address that can be used to submit comments on CHIPRA quality measure development as the process of identifying the initial core measure set proceeds. Subcommittee meeting minutes will be available within 21 business days after the meeting.

Dated: August 13, 2009.

**Carolyn M. Clancy,**

*Director.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2009–N–0374]

#### Educating the Public About Removal of Essential-Use Designation for Epinephrine; Public Workshop; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public workshop entitled “Educating the Public About Removal of Essential-Use Designation for Epinephrine.” The currently approved over-the-counter (OTC) epinephrine metered-dose inhalers (MDIs) contain chlorofluorocarbons (CFCs) and cannot be marketed after December 31, 2011. This 1-day public workshop is intended to seek input from key stakeholders in the asthma community, the pharmaceutical industry, experts in health care communication, and the public on strategies to educate consumers about the decision to remove epinephrine MDIs from the market and transition consumers to therapeutic alternatives that do not contain CFCs or other ozone-depleting substances (ODSs). The agency encourages individuals, patient advocates, industry, consumer groups, health care professionals, researchers, and other interested persons to attend this public workshop.

**DATES:** The public workshop will be held on September 25, 2009, from 8:30 a.m. to 3 p.m. However, depending on public participation, the meeting may be extended or may end early. See section III of this document for information on how to register for the workshop. Written or electronic comments must be submitted by November 24, 2009.

**ADDRESSES:** The public workshop will be held at FDA's, Center for Drug Evaluation and Research Advisory Committee Conference Room, 5630 Fishers Lane, rm. 1066, Rockville, MD 20852.

Submit written or electronic requests to make a presentation to Faith Dugan (see **FOR FURTHER INFORMATION CONTACT**). Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. All comments should be identified with the

docket number found in brackets in the heading of this document.

#### **FOR FURTHER INFORMATION CONTACT:**

Faith Dugan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6182, Silver Spring, MD 20993–0002, 301–796–3446, FAX: 301–847–8752, e-mail:

[Faith.Dugan@fda.hhs.gov](mailto:Faith.Dugan@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Under the Montreal Protocol on Substances that Deplete the Ozone Layer (Montreal Protocol) and the Clean Air Act,<sup>1</sup> 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. Products containing an ODS, such as CFCs, that are not designated as essential uses cannot be sold or distributed in the United States. In the **Federal Register** of November 19, 2008 (73 FR 69532) (the final rule), we amended our regulation on the use of ODSs in self-pressurized containers to remove the essential-use designation for MDIs containing epinephrine. Epinephrine MDIs containing an ODS cannot be marketed after December 31, 2011. You may find copies of the final rule on the Internet at <http://www.regulations.gov>.

Epinephrine is a short-acting adrenergic bronchodilator used in the treatment of asthma. A new drug application (NDA) for OTC epinephrine MDIs was approved in 1956. Epinephrine was designated as an essential use in 1978 (43 FR 11301, March 17, 1978). Epinephrine MDIs are marketed OTC as PRIMATENE MIST and as generic brands for certain retail pharmacies. Epinephrine MDIs are the only MDIs for treatment of asthma (or any other disease) that are approved for OTC use. Consumers do not need a prescription from a health care provider to purchase OTC epinephrine MDIs.

In removing the essential-use designation for epinephrine, we applied the criteria 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 even though the active moiety is not available in a non-CFC product 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;

<sup>1</sup> Montreal Protocol on Substances that Deplete the Ozone Layer, September 16, 1987, 26 I.L.M. 1541 (1987); 1990 Amendments to the Clean Air Act, Public Law No. 101–549 (November 15, 1990).

(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.”

In a proposed rule published on September 20, 2007 (72 FR 53711), we proposed an effective date for removal of the essential-use designation for OTC epinephrine MDIs of December 31, 2010, and we solicited comments on this proposed effective date. We received a number of comments on the effective date and on the related issue of ensuring adequate time to transition consumers who use OTC epinephrine MDIs to non-CFC alternatives. After considering the comments, we were persuaded that December 31, 2011, rather than December 31, 2010, as proposed, is a more appropriate effective date for this rule. The December 31, 2011, date provides additional time to disseminate information about the transition to OTC epinephrine MDI users and allows consumers more time to transition to appropriate non-CFC alternatives. Although at least one manufacturer has stated its intent to develop an OTC epinephrine MDI without CFCs,<sup>2</sup> there is no assurance that the product will be available by December 31, 2011. Thus, we assume that OTC epinephrine MDI users will need to transition to therapeutic alternatives that contain a different active moiety, such as prescription albuterol MDIs.

## II. Scope of Public Workshop

FDA is holding this public workshop to obtain information about usage of OTC epinephrine MDIs and to discuss the best methods for disseminating information to consumers who use these MDIs about the need to transition to alternative treatments for asthma. At the public workshop, FDA will provide relevant background information, including a brief summary of the Montreal Protocol, the Clean Air Act, and the epinephrine final rule. FDA also will present an update on the current transition from CFC MDIs to non-CFC alternatives and FDA's related outreach efforts. Presentations by patient outreach experts and other stakeholders will provide a framework for discussion

about OTC use of epinephrine and how best to educate epinephrine users about the phase-out and therapeutic alternatives. The input from the public workshop will help FDA in developing further outreach and education campaigns to assist consumers in the transition away from OTC epinephrine MDIs.

### A. Objectives of the Workshop

The workshop objectives are as follows:

1. Provide an overview of the regulatory framework for the transition and FDA's current outreach activities.
2. Discuss what is known about current OTC epinephrine MDI usage and the demand for OTC epinephrine MDIs.
3. Discuss the therapeutic alternatives to OTC epinephrine MDIs.
4. Discuss how best to educate consumers who use OTC epinephrine MDIs about the phase-out and therapeutic alternatives.

### B. Issues for Comment

FDA is interested in obtaining public comment on the following issues relating to the transition from OTC epinephrine MDIs to therapeutic alternatives that do not contain ozone-depleting substances:

1. What is known about current OTC epinephrine MDI usage? Who uses them and under what circumstances?
2. What sales data are available and what do they indicate about use of OTC epinephrine MDIs?
3. What treatment alternatives are available for consumers who must switch from OTC epinephrine MDIs?
4. What are effective outreach strategies for informing consumers who use OTC epinephrine MDIs about the transition?
5. What other education efforts should FDA undertake to effect an orderly transition?

## III. Registration

Interested parties are encouraged to register early because space is limited and seating will be on a first-come, first-served basis. There is no fee to attend the public workshop. If you would like to make an oral presentation during the open public session of the workshop, you must register and provide an abstract of your presentation by close of business on September 11, 2009. To register to attend or speak at the public workshop, submit your name, title, business affiliation (if applicable), address, telephone and fax numbers, and e-mail address to Faith Dugan (see **FOR FURTHER INFORMATION CONTACT**). FDA has included questions for

comment in section II of this document. You may identify by number each question you wish to address in your presentation and the approximate time requested for your presentation. FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and to request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin. Persons registered to make an oral presentation should check in at the registration table at 8 a.m.

If you need special accommodations due to a disability, please contact Faith Dugan (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

## IV. Comments

Regardless of attendance at the public workshop, interested persons may submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments should 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.

## V. Transcripts

Transcripts of the public workshop 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 45 working days after the public workshop at a cost of 10 cents per page. A transcript of the public workshop will be available on the Internet at <http://www.regulations.gov>.

Dated: August 13, 2009.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

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<sup>2</sup> See Comment from Mr. Robert Sussman on behalf of Armstrong Pharmaceuticals, Inc., submitted in response to the Proposed Rule on Use of Ozone-Depleting Substances; Removal of Essential-Use Designation (Epinephrine) at 1-2 (dated November 21, 2007) (Document ID FDA-2007-N-0314-0032, available on the Internet at <http://www.regulations.gov>).