(equipment number M10055) with a modified fuel control assembly, install the secondary override pump control relays for the center tank fuel pumps in the P33 and P37 relays panels, and do all other specified actions as applicable, by accomplishing all of the applicable actions specified in the applicable service bulletin. The other specified actions must be accomplished before further flight after installing the secondary override pump control relays.

**Concurrent Modification of the M10055 Fuel Control Panel Assembly**

(l) For airplanes identified in paragraph 1.A.1. of Boeing Alert Service Bulletin 757–28A0105, Revision 1, dated April 2, 2007, equipped with any fuel control panel assembly identified in paragraph 1.A. of BAE Systems Service Bulletin 233N3206–28–03, dated October 4, 2006: Before or concurrently with accomplishing the actions required by paragraph (k) of this AD, modify the fuel control panel assembly, in accordance with BAE Systems Service Bulletin 233N3206–28–03, dated October 4, 2006.

**AWLs Revision for AWL No. 28–AWL–26**

(m) Before or concurrently with accomplishing the actions required by paragraph (k) of this AD: Revise the AWLs section of the Instructions for Continued Airworthiness by incorporating AWL No. 28–AWL–26 of Boeing Temporary Revision (TR) 09–006, dated January 2007, into the MPD. Boeing TR 09–006 is published as Section 9 of the Boeing 757 MPD Document, D622N001–9, Revision January 2007. Accomplishing the revision in accordance with a later revision of the MPD is an acceptable method of compliance if the revision is approved by the Manager, Seattle ACO.

**Terminating Action for AD 2002–24–51**

(n) Accomplishing the actions required by paragraphs (g), (h), (i), and (j) of this AD terminates the AFM limitations required by paragraph (e) of AD 2002–24–51 for Model 757–200, –200CB, –200PF, and –300 series airplanes that have the automatic shutoff system installed, except for the following limitation:

''Warning—Do not reset a tripped fuel pump circuit breaker.''

Except for this limitation, all other AFM limitations required by paragraph (e) of AD 2002–24–51 for Model 757–200, –200CB, –200PF, and –300 series airplanes may be removed from the AFM after accomplishing the actions required by paragraphs (g), (h), (i), and (j) of this AD.

**Credit for Actions Done According to Previous Issue of Service Bulletin**

(o) Actions accomplished before the effective date of this AD in accordance with Boeing Alert Service Bulletin 757–28A0105, dated January 31, 2007, are considered acceptable for compliance with the corresponding actions specified in paragraph (k) of this AD.

**Alternative Methods of Compliance (AMOCs)**

(p)(1) The Manager, Seattle ACO, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(3) Installation of TDG Aerospace, Inc. Universal Fault Interrupter (UFI), installed and maintained in accordance with Supplemental Type Certificate (STC) ST01950LA, is approved as an AMOC with paragraphs (a) through (m) of this AD.

**Note 4:** Information concerning the existence of approved AMOCs with this AD, if any, may be obtained from the Seattle ACO.

Issued in Renton, Washington, on June 25, 2007.

**Ali Bahrami,**

*Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. E7–13265 Filed 7–6–07; 8:45 am]

**BILLING CODE 4910–13–P**

## 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:

- 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 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 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,

[1] ''HFA'' is used in the pharmaceutical industry, and is used here, to refer to the hydrofluoroalklane HFA–134a, a non-ozone-depleting propellant.

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. E7–13300 Filed 7–6–07; 8:45 am]

**BILLING CODE 4160–01–S**

## AGENCY FOR INTERNATIONAL DEVELOPMENT

### 22 CFR Part 201

**[USAID Regulation 1]**

**RIN 0412–AA–51**

## Rules and Procedures Applicable to Commodity Transactions Financed by USAID: Miscellaneous Amendments

**AGENCY:** U.S. Agency for International Development.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The U.S. Agency for International Development (USAID) proposes to amend its regulation governing commodity transactions that are financed by USAID to:

1. Revise the criteria for noncompetitive procurement for private-sector programs to more closely reflect private-sector practices; 2. revise the commodity and package marking requirements to address the use of the new USAID Identity; 3. revise and add definitions to better specify the terminology used; 4. revise agency organizational names and acronyms to specify the current USAID usage; 5. reinstate § 201.13 coverage on ocean transportation costs because it was inadvertently deleted from prior editions; 6. provide for advertising public-sector procurements over $25,000 in the USAID Procurement Bulletins as the primary means of advertising these procurements to U.S. suppliers (in lieu of advertising public-sector procurements over $100,000 in ''FedBizOpps,'' the successor to ''Commerce Business Daily'') to facilitate prompt public notification of procurement opportunities and minimize government expense in providing notice; 7. make numerous clarifications and editorial amendments to better specify the regulation; and 8. specify the current Paperwork Reduction Act approval expirations, as required by the Act.

**DATES:** Submit comments on or before September 7, 2007.

**ADDRESSES:** submit comments by any of the following means:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions there for submitting comments.
- *Fax:* (202) 216–3395.
- *Mail:* USAID, Office of Acquisition and Assistance, Policy Division, Room 7.9–18, 1300 Pennsylvania Avenue, NW., Washington, DC 20523–0001.

*Instructions:* All submissions must include the title of the proposed action, and Regulatory Information Number (RIN) for this rulemaking. Please include your name, title, organization, postal address, telephone number, and e-mail address in the text of the message.

**FOR FURTHER INFORMATION CONTACT:** Kenneth Monsess, Telephone: (202) 712–4913, E-mail: *kmonsess@usaid.gov.*

**SUPPLEMENTARY INFORMATION:**

*Public Participation:* Because security screening precautions have slowed the delivery and dependability of surface mail to USAID/Washington, USAID recommends sending all comments to the Federal eRulemaking Portal listed above (all comments must be in writing to be reviewed).

All comments will be made available for public review without change, including any personal information provided, from three days after receipt to finalization of rule at *http://www.Regulations.gov.*

*Order of Precedence:* The procurement of commodities and commodity-related services by other parties that are financed by USAID pursuant to 22 CFR part 201, as opposed to those that are procured by USAID, are not normally subject to 48 CFR chapters 1 and 7 (the Federal Acquisition Regulation [FAR] and the USAID Acquisition Regulation [AIDAR]). In exceptional circumstances where this part 201 is made applicable, pursuant to § 201.02, to a transaction that is subject to 48 CFR chapters 1 and 7, the latter shall take precedence in areas of conflict except under authority of a FAR or AIDAR deviation pursuant to 48 CFR 1.4 or 48 CFR 701.4; and § 201.02 has been clarified to so state.

*Executive Order 12866 determination:* This rule is significant under Executive Order 12866 and has been reviewed by the Office of Management and Budget. The rule has been reviewed in accordance with the Regulatory Flexibility Act. USAID has determined that the rule will not have a significant economic impact on a substantial number of small entities, and therefore a Regulatory Flexibility Analysis is not required.

*Paperwork Reduction Act statement:* OMB approvals for information collections under this regulation are addressed in § 201.03 and Appendices A and B to part 201.

### List of Subjects in 22 CFR Part 201

Administrative practice and procedure, Commodity procurement, Foreign relations.

For the reasons set out in the preamble, USAID proposes to amend 22 CFR part 201 as follows: