

on these figures, the estimated cost of the proposed AD for U.S. operators is between \$160 and \$640, or between \$80 and \$320 per airplane.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and
3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The Federal Aviation Administration (FAA) amends § 39.13 by adding the following new airworthiness directive (AD):

Boeing: Docket No. FAA-2007-0254; Directorate Identifier 2007-NM-209-AD.

Comments Due Date

(a) The FAA must receive comments on this AD action by January 14, 2008.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Boeing Model 777-200, -200LR, -300, -300ER series airplanes, certificated in any category; as identified in Boeing Alert Service Bulletin 777-31A0119, Revision 1, dated March 27, 2007; and Boeing Alert Service Bulletin 777-31A0120, Revision 1, dated March 23, 2007.

Unsafe Condition

(d) This AD results from an investigation that revealed that detrimental effects could occur on certain airplane information management system (AIMS) software during flight. We are issuing this AD to prevent an unannounced loss of cabin pressure. If an undetected loss of pressure event were to cause an unsafe pressure in the cabin, the flight crew could become incapacitated.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Software Installation

(f) Within 15 months after the effective date of this AD, do the actions specified in paragraphs (f)(1) and (f)(2) of this AD, as applicable.

(1) Install the AIMS Blockpoint 2006 (BP06) operational software by doing all the actions in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 777-31A0119, Revision 1, dated March 27, 2007; or Boeing Alert Service Bulletin 777-31A0120, Revision 1, dated March 23, 2007; as applicable.

(2) Prior to or concurrently with accomplishing the software installation, install the AIMS Blockpoint 2005A (BP05A) software in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 777-31-0098, Revision 1, dated May 3, 2007; or Boeing Special Attention Service Bulletin 777-31-0097, Revision 3, dated February 22, 2007; as applicable.

Credit for Actions Done Using Previous Service Information

(g) Actions accomplished before the effective date of this AD in accordance with

Boeing Alert Service Bulletin 777-31A0119, or Boeing Alert Service Bulletin 777-31A0120, both dated October 16, 2006, are considered acceptable for compliance with the corresponding actions specified in this AD.

Alternative Methods of Compliance (AMOCs)

(h)(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, 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.

Issued in Renton, Washington, on November 20, 2007.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E7-23117 Filed 11-27-07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 347 and 352

[Docket No. 1978N-0038] (formerly 78N-0038)

RIN 0910-AF43

Sunscreen Drug Products for Over-The-Counter Human Use; Proposed Amendment of Final Monograph; 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 December 26, 2007, the comment period for the August 27, 2007, proposed rule to amend the final monograph for over-the-counter (OTC) sunscreen drug products (72 FR 49070). The comment period for the proposed rule was to end on November 26, 2007. The agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: Submit written or electronic comments by December 26, 2007.

ADDRESSES: You may submit comments, identified by Docket No. 1978N-0038

and RIN number 0910–AF43, 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 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 in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name, 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 “Request for Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, 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: Matthew R. Holman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5414, Silver Spring, MD 20993, 301–796–2090.

SUPPLEMENTARY INFORMATION:

I. Discussion

In the **Federal Register** of May 21, 1999 (64 FR 27666), FDA published the final monograph for OTC sunscreen drug products in part 352 (21 CFR part 352) with an effective date of May 21, 2001. Issues concerning active ingredients, labeling, and test methods for products intended to provide ultraviolet A (UVA) protection were deferred for future regulatory action because more time was required to review comments from interested parties. In the **Federal Register** of June 8, 2000 (65 FR 36319), FDA reopened the administrative record of the rulemaking for OTC sunscreen drug products to allow for specific comment on high sun protection factor (SPF) and UVA radiation testing and labeling issues. FDA also extended the effective date for the final monograph to December 31, 2002.

In the **Federal Register** of December 31, 2001 (66 FR 67485), FDA stayed the December 31, 2002, effective date of the final monograph for OTC sunscreen drug products in part 352 pending further notice from FDA in a future issue of the **Federal Register**. FDA took this action because we planned to amend part 352 to address formulation, labeling, and testing requirements for both ultraviolet B (UVB) and UVA radiation protection. The existing stay of the effective date for part 352 remains in effect at this time.

In the **Federal Register** of August 27, 2007 (72 FR 49070), FDA issued a proposed rule that would amend the final monograph for OTC sunscreen drug products to address both UVB and UVA testing and labeling requirements for sunscreen and sunscreen-skin protectant combination drug products. FDA requested comments on the proposed amendments. FDA also requested comments on issues related to OTC sunscreen drug products containing alpha hydroxy acids or titanium dioxide and zinc oxide formulated in particle sizes as small as a few nanometers. The comment period on the proposed rule was scheduled to end on November 26, 2007.

II. Extension of the Comment Period

The agency has received requests for an extension of the comment period for the proposed rule. Each request conveyed concern that the current 90-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the proposed rule.

FDA has considered the requests and is extending the comment period for the proposed rule for 30 days, until December 26, 2007. The agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

In response to several requests to extend the comment period, we are extending the comment period for 30 days, until December 26, 2007.

III. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on this document. 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.

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by us through the FDMS only. When the exact date of the transition to FDMS is known, we will publish a **Federal Register** notice announcing that date.

IV. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) under Docket No. 1978N–0038 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Comment No. EXT10.
2. Comment No. EXT11.
3. Comment No. EXT12.
4. Comment No. EXT13.
5. Comment No. EXT14.
6. Comment No. EXT15.
7. Comment No. EXT16.
8. Comment No. EXT17.
9. Comment No. EXT18.

Dated: November 21, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. 07–5853 Filed 11–26–07; 9:25 am]

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