

online instructions for submitting comments.

Instructions: All submissions must include the agency name and docket number or Regulatory Identification Number (RIN) for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see the Public Participation heading of the **SUPPLEMENTARY INFORMATION** section of this document. Note that all comments received will be posted without change to <http://dms.dot.gov>, including any personal information provided. Please see the Privacy Act heading under **SUPPLEMENTARY INFORMATION** and Regulatory Notices.

FOR FURTHER INFORMATION CONTACT: Katherine Perfetti, AFS-200, 800 Independence Ave. SW., Washington, DC 20591 (202) 267-3760, facsimile at (202) 267-5229, or by e-mail: Katherine.Perfetti@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

By **Federal Register** notice of February 3, 2003 (68 FR 5488), the FAA announced a comprehensive regulatory review and rewrite of parts 135 and 125. It noted that issues under review may include:

a. Design and manufacture of new aircraft that current regulations do not address adequately (for example, large airships, powered lift aircraft).

b. Certain large airplanes with modifications to payload capacity and passenger seat configuration operating under part 91 or 135.

c. New equipment and technologies not adequately addressed in current regulations.

d. International harmonization, ICAO commercial standards, and increased international operations.

The FAA invited members of the public to serve on the Part 135/125 Aviation Rulemaking Committee and/or work groups by notifying the person listed in the notice before March 5, 2003. In addition, the notice solicited comments from the public to docket number FAA-2003-13923 to be filed on or before June 3, 2003.

The Part 125/135 Aviation Rulemaking Committee met on June 10-12, 2003, in Herndon, Virginia to review the docket and to assign the issues posted there to the various work groups. At the opening session of the meeting on June 10, some members requested that the docket be reopened for receiving additional public comments. The FAA agrees with the reopening of the docket and publishes this notice to advise the public of the extended

opportunity to comment on or provide any issues pertinent to this review. The reopened comment period will close on November 18, 2003, because the third meeting of the committee is planned for November 19-21, 2003.

Public Participation

The FAA invites interested parties to submit specific, detailed written comments, or provide input on issues pertinent to parts 125 and 135. All comments submitted to the docket before November 18, 2003, will be considered in the committee discussions.

Privacy Act

Anyone is able to search the electronic form of all comments received into our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Statement in the **Federal Register** published on April 11, 2000 (volume 65, Number 70, pages 19477-78), or you may visit <http://dms.dot.gov>.

Public Web Site

The FAA also reminds the public that a public Web site, <http://www.faa.gov/avr/arm/part135/index.cfm> has been established to provide information on the committee and the review. As part of that website, the FAA provides a list of members of the committee who may be contacted for additional information on a specific area of the review and information on future meetings of the committee.

Issued in Washington, DC on July 9, 2003.

John M. Allen,

Acting Director, Flight Standards Service.

[FR Doc. 03-18070 Filed 7-16-03; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 348

[Docket No. 78N-0301]

RIN 0910-AA01

External Analgesic Drug Products for Over-the-Counter Human Use; Reopening of the Administrative Record and Amendment of Tentative Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is reopening the administrative record for the rulemaking for over-the-counter (OTC) external analgesic drug products to accept comments and data concerning OTC external analgesic drug products that have been filed with the Division of Dockets Management, FDA, since the administrative record officially closed. FDA is also amending the tentative final monograph (TFM) (proposed rule) to clarify the status of patch, plaster, and poultice dosage forms for OTC external analgesic drug products. FDA is providing for the administrative record to remain open for 90 days to allow for public comment on the comments and data being accepted into the rulemaking and on the status of patch, plaster, and poultice dosage forms for OTC external analgesic drug products. This action is part of FDA's ongoing review of OTC drug products.

DATES: Submit written or electronic comments and data by October 15, 2003. See section IX of this document for the effective date of any final rule that may be published based on this proposal.

ADDRESSES: Submit written comments and data 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.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2307.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has on numerous occasions received new data and information bearing on OTC drug panel reports and proposed monographs after the closing of the administrative record in a rulemaking proceeding. Under § 330.10(a)(7)(iii) (21 CFR 330.10(a)(7)(iii)), new data and information may be submitted within 12 months after publication of a TFM. Within 60 days after this 12-month period ends, comments on the new data and information may be submitted (see § 330.10(a)(7)(iv)). Under § 330.10(a)(10)(i), the administrative record closes at the end of this 60-day period.

In the **Federal Register** of February 8, 1983 (48 FR 5852), FDA published the TFM on OTC external analgesic drug products for OTC human use. The