Administration proposes to amend part 39 of the Federal Aviation Regulations (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. Section 39.13 is amended by adding the following new airworthiness directive:

McDonnell Douglas: Docket 2002–NM–06–AD.

Applicability: Model MD–11 and –11F airplanes, as listed in Boeing Service Bulletin MD11–55–023, dated November 28, 2001, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent corrosion of the barrel nut holes of the upper spar caps and skin panel of the horizontal stabilizer, which could result in structural damage and consequent reduced controllability of the airplane, accomplish the following:

One-Time Inspection/ Follow-on and Corrective Actions

(a) Within 18 months or 6,000 flight hours after the effective date of this AD, whichever is later: Do a one-time detailed inspection of the barrel nut holes of the upper spar caps and skin panel of the horizontal stabilizer for corrosion, per Boeing Service Bulletin MD11–55–023, including Appendix A, dated November 28, 2001, and excluding Evaluation Form. Before further flight, do the actions required by paragraph (a)(1), (a)(2), (a)(3), or (a)(4) of this AD, as applicable.

Note 2: For the purposes of this AD, a detailed inspection is defined as: "An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required."

(1) If no corrosion is found: Clean, seal, and tape the barrel nut holes per Figure 4 of the service bulletin.

(2) If corrosion is found that does not exceed the limits specified in Figure 2 of the service bulletin. Remove and retain the barrel nuts and bolts, remove the corrosion of the barrel nut hole, seal and tape the holes per Figure 4 of the service bulletin, and reinstall the barrel nuts and bolts per Figure 2 of the service bulletin.

(3) If corrosion is found that does not exceed 0.060 inch on the barrel nut bottom: Remove and retain the barrel nuts and bolts, remove the corrosion, fabricate and install bushings, seal and tape the holes per Figure 4 of the service bulletin, and reinstall the barrel nuts and bolts per Figure 2 of the service bulletin.

(4) If corrosion is found in the barrel nut bearing area, and/or corrosion exceeds the dimensional limits for each hole specified in Figure 2 of service bulletin: Repair in accordance with a method approved by the Manager, Los Angeles Aircraft Certification Office (ACO), FAA.

Alternative Methods of Compliance

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Los Angeles ACO. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Los Angeles ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles ACO.

Special Flight Permit

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on May 22, 2003.

Vi L. Lipski,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc 03–13385 Filed 5–28–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 333

[Docket No. 75N–183H]

RIN 0910–AA01

Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Health-Care Antiseptic Drug Products; Reopening of the Administrative Record

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of the administrative record.

SUMMARY: The Food and Drug Administration (FDA) is reopening until August 27, 2003, the administrative record for the rulemaking for over-the-counter (OTC) topical antimicrobial drug products to accept comments and data concerning OTC health-care antiseptic drug products that have been filed with the Dockets Management Branch, FDA, since the administrative record officially closed. The agency is also providing for the administrative record to remain open until August 27, 2003, to allow for public comment on the comments and data being accepted into the rulemaking. This action is part of FDA's ongoing review of OTC drug products.

DATES: Submit written comments and data or electronic comments by August 27, 2003.

ADDRESSES: Submit written comments and data to the Dockets Management Branch (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: Michelle M. Jackson, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

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 tentative

final monograph (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.

FDA published an amended TFM on OTC topical antimicrobial health-care antiseptic drug products for OTC human use on June 17, 1994 (59 FR 31402). The administrative record for this TFM closed on August 17, 1995. Under § 330.10(a)(7)(v), new data and information submitted after August 17, 1995, prior to the establishment of a final monograph (FM), are considered a petition to amend the monograph and are to be considered only after a FM has been published unless the agency finds that good cause has been shown that warrants earlier consideration. Further, under § 330.10(a)(10)(ii), the agency shall make all decisions and issue all orders under § 330.10 in the FM solely on the basis of the administrative record and shall not consider data or information not included as part of the administrative record.

FDA has received new data and information submitted to the antimicrobial rulemaking after the administrative record closed on August 17, 1995. In some cases, interested persons submitted a petition to reopen the record. In other cases, they submitted new data and information to the Dockets Management Branch as comments on the amended TFM. A number of the petitions and comments submitted to the amended TFM contain new data on proposed nonmonograph (Category II and Category III) ingredients and on the proposed final formulation testing criteria for health-care antiseptic drug products.

Because these data are relevant to the final classification of these ingredients and to the testing criteria to be established in the FM, FDA has determined that good cause exists to consider these new data and information in developing the FM for these products. By this document, FDA announces that it is treating all of these submissions, received after the administrative record closed, as petitions to reopen the administrative record, and is granting the petitions by allowing the new data and information contained therein to be included in the administrative record for the rulemaking for OTC topical antimicrobial health-care antiseptic drug products.

In response to the TFM, the agency received three citizen petitions concerning ingredients that lacked marketing history for the requested use in the United States to be eligible for the OTC drug review (Refs. 1, 2, and 3). The agency has developed a process by which drugs without any marketing experience in the United States could be eligible for consideration in the agency's OTC drug review. This process is described in 21 CFR 330.14. The petitioners were informed to use that process (Refs. 4, 5, and 6). Thus, these citizen petitions are not included as part of the reopening of the administrative record.

II. Reopening of the Administrative Record

Accordingly, the agency is reopening the administrative record for this rulemaking to accept data and information previously submitted to the Dockets Management Branch into the administrative record and to provide interested persons an opportunity to submit comments on these data and information prior to the closing of the record.

The agency is providing a period of 90 days for these comments and new data and information to be submitted. Interested persons have already had an opportunity to submit comments, objections, or requests for an oral hearing on the amended TFM. Therefore, any comments at this time should only address the data and information submitted to the administrative record after August 17, 1995, and should specifically identify the data and information on which the comments are being provided. In addition, only new information related to the submissions being included in the administrative record at this time should be submitted. Any data and information previously submitted to this rulemaking need not be resubmitted. In establishing an FM, the agency will consider only comments, data, and information submitted prior to the closing of the administrative record following this current reopening.

III. Request for Comments

Three copies of all written comments are to be submitted. Individuals submitting written comments or anyone submitting electronic comments may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IV. References

The following references have been placed on display in the Dockets Management Branch (see **ADDRESSES**) under Docket No. 75N–183H and may be see by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1 Comment No. CP1.
2. Comment No. CP8
3. Comment No. CP13.
4. Comment No. LET23.
5. Comment No. LET24.
6. Comment No. LET33.

Dated: May 19, 2003

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–13317 Filed 5–28–03, 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Chapter I

First Meeting of the Negotiated Rulemaking Committee Established Under the No Child Left Behind Act of 2001

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Announcement of negotiated rulemaking committee meeting.

SUMMARY: The Secretary of the Interior has established a Committee to develop recommendations for proposed rules for Indian education under six sections of The No Child Left Behind Act of 2001. As required by the Federal Advisory Committee Act, we are announcing the date and location of the first meeting of the Negotiated Rulemaking Committee.

DATES: The Committee's first meeting will be held from June 9 to 13, 2003, in Albuquerque, New Mexico.

ADDRESSES: The meeting will be held at the Hyatt Regency Albuquerque, 330 Tijeras Avenue NW., Albuquerque, New Mexico.

FOR FURTHER INFORMATION CONTACT: Barbara James or Shawna Smith, No Child Left Behind Negotiated Rulemaking Project Management Office, PO Box 1430, Albuquerque, NM 87103–1430; telephone (505) 248–7241; fax (505) 248–7242; e-mail *bjames@bia.edu* or *ssmith@bia.edu*. We will post additional information as it becomes available on the Office of Indian Education Programs Web site at *http//www.oiep.bia.edu*.

SUPPLEMENTARY INFORMATION: On May 5, 2003, we published a notice in the **Federal Register** (68 FR 23631)

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: JUL 25 2003

FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 75N-183H

TO: Dockets Management Branch, HFA-305

☑ The attached material should be placed on public display under the above referenced Docket No.

☑ This material should be cross-referenced to Comment No. CP7

Charles J. Ganley, M.D.

Attachment