

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 seen 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.

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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)