DEPARTMENT OF HEALTH AND HUMAN SERVICES

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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 [*insert date 90 days after date of publication in the* **Federal Register**], 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 [*insert date 90 days after date of publication in the* **Federal Register**], 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 [*insert date 90 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written comments and data to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm.

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NEC

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: 5/19/03

May 19, 2003.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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