

of the OTC drug review on May 11, 1972, a date that was later extended to on or before December 4, 1975 (see § 330.13).

2. Such product does not constitute a hazard to health.

3. The product formulation is not regarded to be a prescription drug within the meaning of section 503(b) of the act (21 U.S.C. 353(b)).

4. The product is an OTC drug and does not bear claims for serious disease conditions that require the attention and supervision of a licensed practitioner.

To be considered in this review, eight copies of the data and information must be submitted, preferably bound, indexed, and on standard size paper (approximately 8½ by 11 inches). FDA suggests that all submissions be in the format described in § 330.10(a)(2).

In accordance with § 330.10(a)(2), FDA will handle all submitted data and information as confidential except the general comments submitted to the docket in response to this notice and the answers to the questions and specific information requested on phenazopyridine HCl in section II.B of this document. FDA wants the answers to the questions and the specific information on phenazopyridine HCl to be publicly available when it reviews this ingredient so that all interested parties will have access to this information and be able to participate fully in the deliberations. However, FDA will put all submitted data and information on public display in the Division of Dockets Management (see **ADDRESSES**) 30 days after publication of any proposed rules resulting from the review of the submitted material, except to the extent that the person submitting it demonstrates that it falls within the confidentiality provisions of 18 U.S.C. 1905, 5 U.S.C. 552(b), or section 301(j) of the act (21 U.S.C. 331(j)). At the time of publication, FDA will provide an address where requests for confidentiality should be submitted.

Data and information should be addressed to the Division of OTC Drug Products (see **ADDRESSES**). Data submitted after the closing of the comment period (see **DATES** section) will not be considered except by petition under 21 CFR 10.30. Interested persons may submit written or electronic comments to the Division of Dockets

Management before the closing date. Three paper copies of all mailed 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VI. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. "Bioassay of Phenazopyridine Hydrochloride for Possible Carcinogenicity," National Cancer Institute Carcinogenesis Technical Report Series No. 99, U.S. Department of Health, Education, and Welfare, Publication No. NIH 78-1349, 1978.

2. Labeling for Uristat (Urinary Pain Relief Tablets).

3. Food and Drug Administration, Compliance Policy Guides, No. 7132b.04, issued October 1, 1980, revised May 22, 1987.

4. Food and Drug Administration, Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health, October 31, 1991.

Dated: December 22, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225-04-8002]

Exchange of Letters Between the Food and Drug Administration and the European Commission and the European Agency for the Evaluation of Medicinal Products Concerning the Sharing of Documents and/or Information Related to Assuring the Safety, Quality, and Efficacy of Pharmaceutical Products Intended for Human or Animal Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of an exchange of letters between FDA and the European Commission and the European Agency for the Evaluation of Medicinal Products (EMA). The participants concluded this exchange of letters on September 12, 2003. These letters express the intentions of FDA, the European Commission, and EMA to continue cooperative activities to further enhance and strengthen communication between the respective organizations and further enhance public health promotion and protection in the European Union and the United States of America.

DATES: The agreement became effective September 12, 2003.

FOR FURTHER INFORMATION CONTACT: Michelle Limoli, European Commission Office of International Programs (HFG-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0908.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and memoranda of understanding between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this exchange of letters.

Dated: December 18, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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