(B) *Depth.* The "Wattenberg J Sand" formation ranges from a depth of 7,600' to 8,400'. The average depth is approximately 8,000'.

(2) A more detailed description of the geographical extent and geological parameters of the designated tight formations is located in the Commission's official file for Docket No. RM79–76, and is also located in the official files of the jurisdictional agency which submitted the recommendation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 357

[Docket No. 79N-0378]

Anthelmintic Drug Products for Over-the-Counter Human Use; Establishment of a Monograph

Correction

In FR Doc. 80–27587 appearing on page 59540 in the issue of Tuesday, September 9, 1980, make the following corrections:

(1) On page 59548, the word "not" should be inserted in the first line of paragraph (c)(1)(iii) of § 357.150 so that the paragraph reads as follows:

"(iii) 'Do not give to infants under 2 years of age or children who weigh less than 25 pounds, without first consulting a physician.' "

(2) In the first line of paragraph (c)(2) of the same section, ". . . gentain . . ." should have read ". . . gentian . . .".

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21 CFR Part 358

[Docket No. 80N-0238]

Wart Remover Drug Products for Over-the-Counter Human use; Establishment of a Monograph

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: This proposed rule would establish conditions under which over-the-counter (OTC) wart remover drug products are generally recognized as safe and effective and not misbranded. The proposed rule, based on the recommendations of the Advisory Review Panel on OTC Miscellaneous External Drug Products, is part of the ongoing review of OTC drug products conducted by the Food and Drug Administration (FDA).

DATES: Comments by January 2, 1981, and reply comments by February 2, 1981.

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Bureau of Drugs (HFD–510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4860.

SUPPLEMENTARY INFORMATION: In accordance with Part 330 (21 CFR Part 330), FDA received on December 10, 1979 a report on wart remover drug products from the Advisory Review Panel on OTC Miscellaneous External Drug Products.

Under § 330.10(a)(6) (21 CFR 330.10(a)(6)), the agency issues (1) a proposed regulation containing the monograph recommended by the Panel, which establishes conditions under which OTC wart remover drugs are generally recognized as safe and effective and not misbranded; (2) a statement of the conditions excluded from the monograph because the Panel determined that they would result in the drugs' not being generally recognized as safe and effective or would result in misbranding; (3) a statement of the conditions excluded from the monograph because the Panel determined that the available data are insufficient to classify these conditions under either (1) or (2) above; and (4) the conclusions and recommendations of the Panel.

The unaltered conclusions and recommendations of the Panel are issued to stimulate discussion, evaluation, and comment on the full sweep of the Panel's deliberations. The report has been prepared independently of FDA, and the agency has not yet fully evaluated the report. The Panel's findings appear in this document as a formal proposal to obtain public comment before the agency reaches any decision on the Panel's recommendations. This document represents the best scientific judgment of the Panel members, but does not necessarily reflect the agency's position on any particular matter contained in it. After reviewing all comments submitted in response to this proposal, FDA will issue a tentative final regulation in the **Federal Register** to establish a monograph for OTC wart remover drug products.

In accordance with § 330.10(a)92), the Panel and FDA have held as confidential all information concerning OTC wart remover drug products submitted for consideration by the Panel. All the submitted information will be put on public display in the Hearing Clerk's Office, Food and Drug Administration, after November 3, 1980, except to the extent that the person submitting it demonstrates that it still falls within the confidentiality provisions of 18 U.S.C. 1905 or section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)). Requests for confidentiality should be submitted to William E. Gilbertson, Bureau of Drugs (HFD–510) (address above).

Based upon the conclusions and recommendations of the Panel, FDA proposes the following:

1. That the conditions included in the monograph, under which the drug products would be generally recognized as safe and effective and not misbranded (monograph conditions), be effective 30 days after the date of publication of the final monograph in the **Federal Register.**

2. That the conditions excluded from the monograph, either because they would cause the drug to be not generally recognized as safe and effective or to be misbranded or because the available data are insufficient to support the inclusion of such conditions in the monograph (nonmonograph conditions), be eliminated from OTC drug products effective 6 months after the date of publication of the final monograph in the **Federal Register,** regardless of whether further testing is undertaken to justify their future use.

FDA published in the **Federal Register,** of May 13, 1980 (45 FR 31422) its proposal to revise the OTC procedural regulations to conform to the decision in *Cutler* v. *Kennedy,* 475 F. Supp. 838 (D.D.C. 1979). The Court in *Cutler* held that the OTC drug regulations (21 CFR 330.10) are unlawful to the extent that they authorize the marketing of Category III drugs after a final monograph. Accordingly, the proposed regulations delete this provision and provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process, before the establishment of a final monograph (45 FR 31422).

Although it was not required to do so under *Cutler,* FDA has also decided to stop using the terms "Category I," "Category II," and "Category III" at the final monograph stage in favor of the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III).