DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 80N-0295]

Over-the-Counter (OTC) Drug Review Policy Statement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces the policy the agency intends to use concerning: (1) the submission and review of proposed protocols to evaluate an ingredient or condition in the over-the-counter (OTC) drug review, (2) meetings with industry or other interested persons, (3) communications by the agency on submissions of test data and other information, and (4) maintenance of a public record involving these activities.

DATE: Comments by November 30, 1981.

ADDRESS: Written comments to the Dockets Management Branch (formerly the Hearing Clerk's Office) (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, 301-443-4960.

SUPPLEMENTARY INFORMATION: Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule revising the procedural regulations in 21 CFR 330.10 for revising and classifying OTC drugs to delete the provision that authorizes the marketing of a Category III ingredient or other condition in an OTC drug product after a final monograph is established. This action is being taken to conform to the holding and order of the United States District Court for the District of Columbia in *Cutler* v. *Kennedy*, 475 F. Supp. 838 (D.D.C. 1979). this revision in the regulations will affect the time period during which new data may be submitted to FDA to support the inclusion in a final monograph of a condition not classified in Category I in a proposed or tentative final monograph.

When FDA issued the OTC drug review regulations in 1972, it concluded that Category III testing should not be required until after publication of the applicable final monograph. Because of the court decision in *Cutler* v. *Kennedy, supra*, any testing necessary to resolve the issues that resulted in a condition not being classified in Category I, and submission of the test data or other available data to FDA to support inclusion of the condition in a final monograph, must be done during the OTC drug rulemaking process, before the establishment of a final monograph.

Under the current OTC drug review procedures, new data may be submitted as part of the comments to a panel report and proposed monograph. After the administrative record has closed, new data or information not previously submitted for inclusion in the administrative record may be submitted for inclusion only with a petition to the Commissioner requesting that the administrative record be reopened to include such material. In the past, such data and information received prior to the publication of a tentative final or final order have been addressed in he appropriate order.

Under the new procedures described in the final rule published elsewhere in this issue of the **Federal Register**, the agency's decision contained in a tentative final monograph will be based solely on the administrative record developed through the 90-day comment and 30-day rebuttal comment period following the proposed monograph. New data and information may be submitted after the 90-day comment period, but will be considered only after the administrative record is reopened following publication of a tentative final monograph. After publishing the tentative final monograph, FDA will reopen the administrative record for 12 months to permit interested persons to submit new data and information in support of the safety and effectiveness of any condition reviewed by a panel and not classified by the agency in Category I. Following a 2-month rebuttal comment period, the administrative record will be closed, and the agency's decision on the conditions to be included in a final monograph will be based solely on the administrative record developed throughout the entire OTC rulemaking period. Any data received by FDA after closing of the administrative record following the tentative final monograph will ordinarily be handled after publication of the final monograph as a petition to amend the monograph, unless the Commissioner finds that good cause has been shown that warrants earlier consideration.

While manufacturers have not been required under current regulations to conduct Category III testing until after completion of the OTC drug administrative procedures, i.e., publication of the final monograph, some firms have conducted such testing during the course of the review and have submitted the data as comments to a published panel report and proposed monograph or as a petition after the comment/reply comment period for the proposed monograph had closed. In the past, such testing did not have to be conducted until a final monograph had been published, and FDA did not comment on the results of this testing until a tentative final monograph was published. Likewise, data were sometimes submitted after a tentative final monograph was published, and FDA did not comment on these data until a final monograph was published. Although, in some instances, FDA may have completed its review of data at an early date, the agency's evaluation of that data would not be made public until the agency had completed its review of all data in the administrative record and had published its conclusions in either a tentative final or final monograph.

Under the revised OTC procedural regulations, all Category III testing must be completed prior to publication of a final monograph, if a manufacturer is interested in upgrading a condition to Category I status before the establishment of a final monograph. Because of the importance of early testing under the new procedures, manufacturers wish to be informed of the status of data previsouly submitted before initiating further studies. Providing this information to interested persons as the agency's reviews of these data are completed should result in earlier testing, where necessary, and the submission of the results earlier to FDA. To the extent possible, the agency plans to inform manufacturers of any tentative determination it has reached that additional data are needed or that the data sumitted are adequate to establish Category I status so that further testing appears unnecessary. Announcing these decisions early in the process will also benefit consumers because additional testing will be encouraged when it is needed, and consumers will know at an earlier date what ingredients have been tentatively recommended for upgrading to Category I status.

FDA staff will also meet with manufacturers, as necessary and as agency resources permit, to discuss testing protocols. FDA hopes to provide this information at an early enough date so that manufacturers can complete any additional necessary studies and can submit the data in the most expeditious fashion possible. Manufacturers should be aware though that their obligation to submit the data necessary to support the movement of a Category III condition to Cateogry I is independent of any information provided by the agency.

Similarly, the agency will not delay the OTC drug review in order to provide this "feedback," but will proceed to the next appropriate publication as soon as it is possible to do so under the procedures detailed in the revised OTC drug procedural regulations published elsewhere in this issue of the **Federal Register.**

FDA will meet with industry representatives at their request to provide information on data already submitted to FDA, to consult on testing guidelines for those conditions which industry is interested in upgrading, and to advise industry on the adequacy of their proposed testing protocols. Any communications between the agency and industry on these matters may continue outside the formal comment periods and will be part of the public record.

Further details are described below.

Protocols and Test Data

All proposed testing protocols and test data will be part of the public record and should be submitted in four copies to the Dockets Management Branch, FDA (address above), in accordance with the OTC drug review administrative procedures in § 330.10. All submissions should make reference to the appropriate docket number. Copies of any acceptable protocols or testing guidelines will also be placed in the Dockets Management Branch under the appropriate docket numbers. Any information that the agency provides sponsors on these test data and protocols will also be publicly available and will be placed in the Dockets Management Branch.

Meetings

Any person wishing to meet with agency representatives to discuss a proposed protocol or data previously submitted to the agency may request such a meeting by contacting the Division of OTC Drug Evaluation (HFD–510) (address and phone number provided above), which is responsible for coordinating all meetings. All such meetings will be open to the public.

Whenever an agency employee meets with a firm, an individual, or group of persons and discusses testing protocols, or data previously submitted to the agency, the FDA employee will make a memorandum of that meeting and the memorandum will be placed in the Dockets Management Branch under the appropriate docket number.

Communications on Submitted Data

Communications to manufacturers concerning submitted data will be of two types. First, as the Bureau of Drugs (Bureau) reviews the data, staff members may find it necessary to request clarification of certain points or to request additional data from the sponsor. The agency employee may request the information by letter or by telephone. A copy of the letter to the manufacturer that submitted the data or a copy of a memorandum of telephone conversation will be placed in the Dockets Management Branch under the appropriate docket number. All data submitted in response to FDA's request for additional information must be submitted to the Dockets Management Branch.

Second, when the Bureau completes its review, it will make a tentative determination that the data submitted are or are not adequate to support a Category I status for the condition. Whenever possible, the Bureau plans to notify the sponsor that the data are inadequate or that it has made a tentative interim decision to recommend to the Commissioner that the condition be upgraded in the next publication of the monograph (tentative final or final monograph) so that further expenses of testing can be eliminated. A copy of the letter informing the manufacturer of the tentative interim decision will also be placed in the Dockets Management Branch so that all other interested manufacturers and consumers will be informed. The agency points out that the Bureau's decision to recommend upgrading of the condition to Category I is only tentative and could change at the time the tentative final or final monograph is published if new information becomes available or if the Commissioner does not accept the Bureau's recommendation. Manufacturers acting in reliance upon this tentative interim decision must act at their own risk.

Public Record

The Bureau of Drug's Division of OTC Drug Evaluation intends to make available in the Dockets Management Branch under Docket Number 80N–0295 a record of information provided to manufacturers so that the interested persons can be aware of all communications that the Bureau has made concerning any Category II or III conditions. Each month the Division of OTC Drug Evaluation will update the list which will itemize each letter, meeting, and protocol, providing the date of the item, the persons involved, and the docket number under which the detailed information may be found. Interested persons are advised to check the Dockets Management Branch routinely to keep informed.

It is important to note the impact of this policy regarding FDA review of data and information and consultation on protocols or testing guidelines. Under this policy a substantial number of communications between FDA and interested persons on the subject of Category III testing will occur and will become a part of the public record. These communications will not be included in the administrative record for the related OTC monograph unless the communication directly influences an agency decision on a particular matter in the monograph or provides the substantiation for the agency's decision on that matter. For example, a protocol or test guideline would not normally become part of the administrative record, but the results of the study, which may also be the subject of one of these communications, would be included in the administrative record because it would be one of the bases for the Commissioner's final decision on the ingredient.

Notice and comment is not necessary before issuing this policy statement. (See 5 U.S.C. 553(b)(B).) Furthermore, the purpose and major aspects of this policy statement were described in the preamble to the May 13, 1980, proposed rule (45 FR 31422) on the agency's Category III regulations for which a final rule is published elsewhere in this issue of the **Federal Register.** It would also be contrary to the public interest to delay implementing the policy described in this policy statement.

Interested persons may, on or before November 30, 1981, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments on this policy statement. Three copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Such comments will be considered in determining whether amendments or revisions to the policy statement are warranted. Received comments will be incorporated into the public file on the statement and may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 7, 1981.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

Dated: September 8, 1981.

Richard S. Schweiker,

Secretary of Health and Human Services.

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