



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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APR 13 2000

Walter N. Kernan, M.D.
Associate Professor of Medicine
Department of Internal Medicine
Yale University School of Medicine
333 Cedar Street
P.O. Box 208025
New Haven, CT 06520-8025

Dear Dr. Kernan:

On October 12, 1999, you notified the Food and Drug Administration (FDA) about partial, preliminary results of a case control study of phenylpropanolamine (PPA) and hemorrhagic stroke that was completed in 1999. During that and subsequent communications with FDA, we discussed when you anticipated completing your final analysis of the study results. We requested that you submit a report to the agency describing the study conduct and results. You were advised that any information submitted would be made available to the public because this is required under the OTC drug monograph review. We also noted that if you determined that a significant safety issue may exist, you were encouraged to promptly file a safety report with the agency. Further, it was discussed that this study would probably be discussed at an open public meeting of the Nonprescription Drugs Advisory Committee (NDAC). On January 13, 2000, we requested that the data from the study also be submitted so that the agency could conduct its own analyses.

PPA is currently marketed as a proposed Category I (generally recognized as safe and effective) ingredient under the recommendations of panel reports for nasal decongestion and as a weight control product. PPA is currently available in several hundred OTC drug products. It has maintained its Category I status, rather than being placed in Category III (available information is insufficient to classify, more testing needed), because of the long history of use of the ingredient and with the agreement of the OTC drug industry to sponsor this study.

Although the agency is sensitive to the difficulties in completing a report, we need to review this information promptly to assist us in finalizing the OTC status of PPA. Because more than five months have elapsed since the time of your initial telephone conversation with the agency, we are requesting that the report and data be submitted as soon as possible. You may also consider submitting the data prior to the submission of your report to allow the agency to initiate its review of the study. Your final study report can then be provided at a later date once you feel comfortable with the final version.

81N-0022

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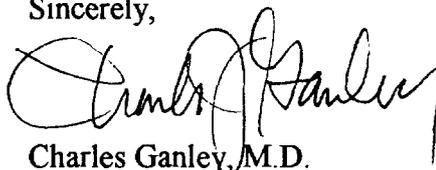
Scheduling of public advisory committee meetings must generally be planned months in advance. Over the past several months, the agency has asked NDAC members to set aside multiple potential dates on their schedules for this meeting. However, the meeting dates could not be finalized because the report and data have not been made available to the agency. As we need to finalize a date for this NDAC meeting in the near future, we are requesting that the information be provided as soon as possible. Alternatively, please provide a firm date when the information will be provided. Your cooperation in this matter is appreciated.

Please submit three copies of the study report to Docket No. 81N-0022. Also submit a letter to Docket No. 76N-052N indicating that the study report was submitted to Docket No. 81N-0022. Please send this information to:

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

If you have any questions regarding the submission of the data from the study, please contact Thomas A. Parmelee, Pharm.D., Regulatory Project Manager at (301) 827-2271. Please let Dr. Parmelee know in the next week when the agency can expect to receive the requested information.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles Ganley". The signature is fluid and cursive, with a large initial "C" and "G".

Charles Ganley, M.D.

Director

Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: APR 13 2000

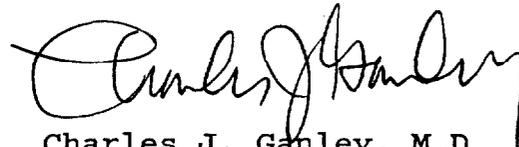
FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 81N-0023

TO: Dockets Management Branch, HFA-305

The attached material should be placed on public display under the above referenced Docket No.

This material should be cross-referenced to Comment No. _____


Charles J. Ganley, M.D.

Attachment