DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

1984 APR -4 PM 2:50

APR - 4 1984

Stephen Kurzman, P.C.
Nixon, Hargrave, Devans and Doyle
1090 Vermont Avenue, N. W. (Suite 1200)
Washington, DC 20005

RE: Docket No. 81N-0022/CP0006 and
Docket No. 76N-0052N/CP0006

Dear Mr. Kurzman:

This is in reply to the citizen petition submitted to the Food and Drug Administration on February 14, 1983, requesting that the administrative records for the OTC weight control drug products and the OTC nasal decongestant drug products rulemakings be reopened to include new data and information on phenylpropanolamine hydrochloride.

The agency has decided to include the data in question in the administrative records for the rulemakings for OTC weight control drug products and OTC nasal decongestant drug products. In the advance notice of proposed rulemaking for OTC weight control drug products, published in the FEDERAL REGISTER of February 26, 1982 (47 FR 8466), the agency stated that it would continue to monitor further studies and information on phenylpropanolamine. The data accompanying your petitions provided additional information regarding the safety of phenylpropanolamine hydrochloride and are currently being reviewed in conjunction with the development of the tentative final monographs (TFM) for OTC weight control drug products and OTC nasal decongestant drug products. The agency considers your petitions to be "feedback" communications.

In the FEDERAL REGISTER of September 29, 1981 (46 FR 47740), announcing the "feedback" policy, the agency stated that "feedback" communications would 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. We also stated that the results of a study would be included when they were one of the bases for the Commissioner's decision on an ingredient. This feedback policy was further clarified in the FEDERAL REGISTER of April 1, 1983 (48 FR 14050). Because the data accompanying your petitions will be used by the agency in reaching a decision on the classification of phenylpropanolamine hydrochloride in the respective TFMs, the agency is including it in the appropriate administrative records at this time.

76N-052N

LET085

Should you have any questions regarding this matter, please refer to the appropriate Docket Numbers above and submit the inquiry in triplicate to the following address:

Dockets Management Branch
Food and Drug Administration
Room 4-62
5600 Fishers Lane
Rockville, MD 20857

Sincerely yours,

William E. Gilbertson, Pharm. D.
Director
Division of OTC Drug Evaluation
Office of Drug Standards
Center for Drugs and Biologics

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO : Dockets Management Branch (HFA-305) DATE: APR - 4 1984

FROM : Director
Division of OTC Drug Evaluation (HFN-510)

SUBJECT: Material for Docket No. 81N-0022 and 76N-0052N

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

☐ This material should be cross-referenced to Comment _____.

Wm E Gilbertson

William E. Gilbertson, Pharm. D.

Attachment

CROSS FILE SHEET

FILE NO: 76N-052N/LET085

SEE FILE NO: 81N-0022/LET036