



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

Gregory M. Fisher  
Associate General Counsel  
The Proprietary Association  
1700 Pennsylvania Avenue, N.W. #700  
Washington, DC 20006

APR 20 1983

Re: Docket No. 76N-052N/CP0002

Dear Mr. Fisher:

This is in reply to your citizen petition submitted to the Food and Drug Administration on January 28, 1983, requesting that the administrative record for the OTC nasal decongestant drug products rulemaking be reopened to include data on phenylpropanolamine recently submitted to the administrative record for OTC weight control drug products.

Ms. Helen Cothran of my staff called you on February 3, 1983 to clarify the data that you were referring to; however, you were not able to specifically identify the data. We believe that you were referring to the same data covered by another recent petition to reopen the administrative records for these two rulemakings to include new data and information on phenylpropanolamine hydrochloride. The agency granted that petition on April 14, 1983 (copy of letter attached). Therefore, no further action is necessary regarding your petition.

I hope this information is helpful.

Sincerely yours,

William E. Gilbertson, Pharm. D.  
Director  
Division of OTC Drug Evaluation  
Office of the Associate Director for  
Drug Monographs  
Office of Drugs  
National Center for Drugs and Biologics

Enclosure

76N-052N

LET082

APR 14 1983

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

Re: Docket No. 81N-0022/CP0002 and  
Docket No. 76N-052N/CP0003

Dear Mr. Kurzman:

This is in reply to the citizen petitions submitted to the Food and Drug Administration on January 11, 1983 and February 18, 1983, requesting that the administrative record for the OTC weight control drug products and the OTC nasal decongestant drug products rulemakings, respectively, 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 information accompanying your petition provides additional data regarding the safety of phenylpropanolamine hydrochloride. These data 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 studies accompanying your petition will be used by the agency in reaching a decision on the classification of phenylpropanolamine hydrochloride in the respective TFMs, the agency is including them in the appropriate administrative records at this time.

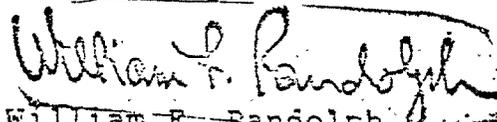
Stephen Kurzman, P.C.

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

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

Sincerely yours,



William F. Randolph  
Acting Associate Commissioner  
for Regulatory Affairs

cc: HF-1  
HF-2  
HF-43  
GCF-1 (2)  
HFA-224  
HFA-305 (Docket No. 81N-0022) and (Docket No. 78N-052N)  
EFC-1  
HFC-2  
HFC-10  
HFN-1  
HFN-7  
HFN-200  
HFN-500  
HFN-510: ING 40.38/DDC 980.3/DDC 370.3/Reading/Rachanow  
HFN-513: Reading/Bader/Cothran  
HFN-514: Reading/Myers/Short  
RD: JShort/2/18/83/lj/2/18/83  
RE-RD: JShort/2/25/83/lj/2/28/83  
END: GRachanow/3/7/83  
END: WGilbertson/3/7/83  
END: GKnappp/3/10/83  
END: MWatson/3/15/83  
END: JHalperin/3/28/83  
END: BRice/4/6/83  
END: KBaumgartner/4/11/83  
FINAL: ljones/4/12/83  
DOC ID 5566C/DISKETTE 079C

*ljones* 4/12/83

**G.R.** 4/12/83

# MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
1983 APR 20 PM 1:18

TO : Dockets Management Branch (HFA-305)      DATE: APR 20 1983

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

SUBJECT: Material for Docket No. 76N-052N



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



This material should be cross-referenced to Comment \_\_\_\_\_.



William E. Gilbertson, Pharm. D.

Attachment