



Stephen Kurzman, P.C.  
Nixon, Hargrave, Devans & Doyle  
One Thomas Circle, N.W., Suite 800  
Washington, DC 20005

JUL 12 1985

Re: Docket No. 81N-0022/CP0009 and  
Docket No. 76N-052N/CP0009

Dear Mr. Kurzman:

This is in response to your citizen petition dated June 20, 1985, and filed with the Dockets Management Branch on June 21, 1985. The petition requested 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 considers your petition to be a "feedback communication" under the OTC Drug Review procedures. It has been placed in the public record but at this time will not be included in the respective administrative records unless these data directly influence or are used by the agency in making a decision on the status of phenylpropanolamine in the OTC weight control drug products or OTC nasal decongestant drug products proposed rule. Announcement of the "feedback policy" was first included in the FEDERAL REGISTER of September 29, 1981 (46 FR 47740), and further clarified in the FEDERAL REGISTER of April 1, 1983 (48 FR 14050). If the data are not used by the agency in preparing these proposed rules, the agency will include them in the administrative records for the respective rulemaking when the administrative records reopen during the comment period following publication of the respective proposed rule. In any event, you may rest assured that the data will be under active review by the agency.

Should you have any questions regarding this matter, please refer to the docket numbers noted above and submit all inquiries in triplicate to the Dockets Management Branch at the address to which you sent your petition.

Sincerely yours,

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

76N-052N

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LET992



Memorandum

Date . JUL 12 1985

From Director  
Division of OTC Drug Evaluation (HFN-210)

Subject: Material for Docket No.

and

~~810-0022/CP0009~~  
~~760-052N/CP0009~~

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 \_\_\_\_\_.

*W-E Gilbertson*

William E. Gilbertson, Pharm. D.

Attachment