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February 24, 1984

Dr. Mark Novitch
Acting Commissioner
Food and Drug Administration
Room 14-17
Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857

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COMMUNICATIONS SECTION

Dear Mark:

The reason I was trying to see you last week was the latest study on phenylpropanolamine, a copy of which is enclosed. It has been filed with the Hearing Clerk with a Citizens Petition.

I understand how busy you are at this point and very much appreciate your trying to get back to me by phone.

Please do call if you have any questions or comments on the study, which, once again, documents the safety of PPA.

With best wishes,

Sincerely,



Stephen Kurzman, P.C.

Enclosure
SK/bh

TRAC #8400492

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February 14, 1984

Dockets Management Branch
Food and Drug Administration
Department of Health and
Human Services
Room 4-62
5600 Fishers Lane
Rockville, Maryland 20857

1984 FEB 16 PM 1:58

CITIZEN PETITION

The undersigned submits this petition on behalf of Thompson Medical Company, Inc. under 21 CFR 10.30 to request the Commissioner of Food and Drugs to open the administrative records in the Over-the-Counter Drug Reviews of Weight Control Drug Products (Docket No. 81N-0022) and Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products (Docket No. 76N-0052N) to accept the enclosed materials relating to the recently-completed study conducted by Paul Robertston, M.D., at the Department of Medicine, University of Washington, Seattle, Washington.

A. Action Requested

The undersigned respectfully requests that the administrative record be opened to permit the enclosed materials to be considered in the referenced OTC Drug Review.

B. Statement of Grounds

The grounds on which petitioner relies are that phenylpropanolamine hydrochloride (PPA) is one of the ingredients of weight control products and nasal decongestants which are the subjects, respectively, of the above-referenced proposed OTC Drug Products Monographs. The Panel Monographs concluded that PPA and its salts are safe and effective for

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OTC weight control and oral nasal decongestant use in the specified dosages. The Tentative Final Monograph has not yet been published in either Review. In the preamble to the Advance Notice of Proposed Rulemaking in the Weight Control Drug Products Review (47 Fed. Reg. 8466, et seq., February 25, 1982), the Commissioner requested further studies regarding the safety of PPA for use in weight control products.

The enclosed materials summarize a study demonstrating the safety of PPA in weight control products. Since the same ingredient is involved in both types of products, the enclosed materials are highly significant to the agency's OTC Drug Reviews of both weight control and cough/cold drug products. Therefore, these materials should be considered in both Reviews at the earliest possible time.

In view of the size of the study report, two copies are enclosed for your convenience, one for each administrative record.

C. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



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THOMPSON MEDICAL COMPANY, INC.

919 THIRD AVENUE • NEW YORK, N.Y. 10022 • (212) 688-4420

February 13, 1984

Dr. Mark Novitch
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Novitch:

Enclosed please find the results of a recently completed clinical study conducted at the Department of Medicine; University of Washington; Seattle, Washington, by Paul Robertson, M.D. This study evaluated blood pressure, pulse, and subjective mood changes for possible adverse symptoms attributable to phenylpropanolamine.

The results are consistent with those reported to you on January 3, 1983 in the study of phenylpropanolamine conducted at Johns Hopkins School of Medicine, as well as the study on phenylpropanolamine reported to you in September of 1983 conducted by Rudolf E. Noble, M.D., Ph.D., at the Cathedral Hill Obesity Clinic.

In this current study, two hundred twenty four (224) healthy normotensive volunteers participated in a double-blind placebo-controlled evaluation of the effects of phenylpropanolamine HCl (PPA) on blood pressure, pulse and mood.

The results of this study clearly indicated that:

- A. Phenylpropanolamine does not affect blood pressure.
- B. Phenylpropanolamine does not raise pulse rate.
- C. Phenylpropanolamine does not have abuse or addictive potential.
- D. Phenylpropanolamine does not affect mood.
- E. Phenylpropanolamine is not a stimulant.

This study reconfirms not only the data from the Johns Hopkins and the Cathedral Hill studies, but also the numerous previously submitted clinical studies which support the claim of safety of phenylpropanolamine in the recommended dose.

We feel that these data definitely support the continued confidence of the agency in maintaining phenylpropanolamine as a Category I drug to help suppress appetite and aid in weight loss.

Thank you for your courtesy and attention.

Sincerely yours,

Edward L. Steinberg, M.Sc., O.D.
Vice Chairman of the Board

ELS:kj
Encl.