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October 13, 1983

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

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 Rudolf E. Noble, M.D., Ph.D., at the Cathedral Hill Obesity Clinic, San Francisco, California.

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 Reviews.

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

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safe and effective for 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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