



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 22 1997

Mr. Daniel N. Horwitz, C.E.O.
Thompson Medical Company, Inc.
222 Lakeview Avenue, 17th Floor
West Palm Beach, Florida 33401-6112

8190 '97 AUG 27 012:16

Re: Docket No. 81N-0022
Comments No. CP10-CP15

Docket No. 76N-052N
Comments No. CP11, CP13,
and CP14

Dear Mr. Horwitz:

This letter concerns your above referenced citizen petitions dated October 6, 1988 (Docket No. 81N-0022, Comment No. CP10, and Docket No. 76N-052N, Comment No. CP11), March 30, 1990 (Docket No. 81N-0022, Comment No. CP11, and Docket No. 76N-052N, Comment No. CP13), August 30, 1990 (Docket No. 81N-0022, Comment No. CP12), November 13, 1990 (Docket No. 81N-0022, Comment No. CP13, and Docket No. 76N-052N, Comment No. CP14), October 5, 1991 (Docket No. 81N-0022, Comment No. CP14), and May, 12, 1992 (Docket No. 81N-0022, Comment No. CP15). The petitions request that the administrative record for the OTC weight control and nasal decongestant drug products be reopened to allow consideration of additional information on the safety and effectiveness of phenylpropanolamine hydrochloride (PPA) for weight control and nasal decongestant use, and the effectiveness of benzocaine for OTC weight control use.

For the reasons given below, the agency considers action on the petition as completed.

This is the agency's final response to the petition.

On July 25, 1996, Debra L. Bowen, M.D., Director, Division of OTC Drug Evaluation, issued a letter to you (copy attached) stating specific reasons why we believe that the agency has, in effect, already granted your petitions. Namely, that the information in the petitions already has been considered in evaluating the safety of PPA for both weight control and nasal decongestant use, and the effectiveness of PPA and benzocaine for weight control use. The information is included in the respective administrative records.

76N-052N

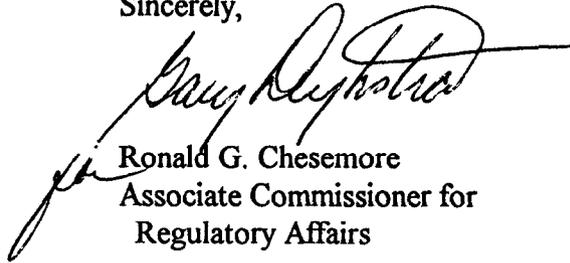
PAVS

Mr. Russ Jones

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If you have any questions regarding the petitions, please refer to the docket numbers above and submit all inquiries, in triplicate, to the Dockets Management Branch, HFA-305, Food and Drug Administration, 12420 Parklawn Drive, Room 1-23, Rockville, MD 20857.

Sincerely,

A handwritten signature in black ink, appearing to read "Ronald G. Chesemore". The signature is written in a cursive style with a long horizontal flourish extending to the right.

Ronald G. Chesemore
Associate Commissioner for
Regulatory Affairs

Enclosure:

July 25, 1996, letter

from Debra Bowen, M.D.

To Daniel N. Horwitz, C.E.O.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 25 1996

Daniel N. Horwitz, C.E.O.
Thompson Medical Company, Inc.
222 Lakeview Avenue, 17th Floor
West Palm Beach, Florida 33401-6112

Re: Docket No. 81N-0022
Comments No. CP10, CP11,
CP12, CP13, CP14, and CP15
Docket No. 76N-052N
Comments No. CP11, CP13, and CP14

Dear Mr. Horwitz:

This is in further response to your company's citizen petitions dated October 6, 1988 (coded CP10, Docket No. 81N-0022, and CP11, Docket No. 76N-052N), March 30, 1990 (coded CP11, Docket No. 81N-0022, and CP13, Docket No. 76N-052N), August 6, 1990 (coded CP12, Docket No. 81N-0022), November 13, 1990 (coded CP13, Docket No. 81N-0022, and CP14, Docket No. 76N-052N), October 5, 1991 (coded CP14, Docket No. 81N-0022), and May 12, 1992 (coded CP15, Docket No. 81N-0022), and filed in FDA's Dockets Management Branch. The petitions requested that the administrative record for the rulemakings for over-the-counter (OTC) weight control and nasal decongestant drug products be reopened to allow consideration of additional data and information on the safety and effectiveness of phenylpropanolamine hydrochloride (PPA) for weight control and nasal decongestant use and the effectiveness of benzocaine for OTC weight control use.

The citizen petitions regarding PPA included three textbooks that provide safety and effectiveness data from published surveys, epidemiological summaries, and clinical studies (CP10), two new double-blind, placebo-controlled clinical studies to demonstrate the effectiveness of PPA for weight control (CP11), a commentary on the testimony on PPA presented to the House Subcommittee on Regulation, Business Opportunities and Energy (CP13), a double-blind, placebo-controlled clinical study to support the safety and effectiveness of PPA as a diet aid (CP14), and an independent analysis of hemorrhagic strokes reportedly associated with PPA use (CP14).

The citizen petitions regarding benzocaine included a new double-blind, placebo-controlled clinical study and other supportive data to demonstrate effectiveness (CP12), two statistical reevaluations of that new study (CP15), and a response to the

agency's review of other studies involving weight control drug products containing benzocaine and caffeine (CP15).

The agency has reviewed the clinical studies and other information included in these petitions to support the effectiveness of PPA and benzocaine for weight control use and PPA for nasal decongestant use and has provided comments in a letter to your company dated May 23, 1991 (LET82, Docket No. 81N-0022), and letters to the Nonprescription Drug Manufacturers Association dated March 9, 1993 and May 20, 1994 (LET86 and LET92, Docket No. 81N-0022).

As you know, agency policy (see the FEDERAL REGISTER of September 29, 1981 (46 FR 47740) and April 1, 1983 (48 FR 14050)) allows "feedback" material that has been submitted after an administrative record has officially closed (as was the situation in this case) to be added to the administrative record without the submission of a formal petition when that material directly influences or forms one of the bases for the agency's decision in an OTC drug rulemaking proceeding. Because the agency considered the information in your company's petitions in evaluating the safety of PPA for both weight control and nasal decongestant use and the effectiveness of PPA and benzocaine for weight control use, the agency has included your petitions in the respective administrative records. Thus, the agency has, in effect, already granted your petitions.

We hope this information will be helpful.

Sincerely,


Debra Bowen, M.D.
Director
Division of OTC Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

M E M O R A N D U M DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: AUG 25 1997

FROM: Director
Division of OTC Drug Products, HFD-560

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

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 No. _____.


Debra L. Bowen, M.D.

Attachment