



Memorandum

MAR 16 1996

Date
From Acting Director, Division of Programs and Enforcement Policy,
Office of Special Nutritionals, HFS-455
Subject 75-Day Premarket Notification for New Dietary Ingredients
To Dockets Management Branch, HFA-305

New Dietary Ingredients: Casimiroa edulis (White Sapote) and
Buddleja americana (Tepozan)
Firm: Malabar Productos Naturales, S.A.DE C.V. E
Date Received by FDA: February 7, 1996
90-Day Date: May 7, 1996

In accordance with the requirements of section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification for the aforementioned new dietary ingredients should be placed on public display in docket number 95S-0316 after May 7, 1996.

RECEIVED AND INDEXED

Sincerely

John W. Gordon
Acting Director, Division of Programs
and Enforcement Policy
Office of Special Nutritionals
Center for Food and Safety
and Applied Nutritionals

95S-0316

RPT 2



RECEIVED BY THE
OFFICE OF SPECIAL
NUTRITIONALS, HFS-450

'96 FEB -7 P3:53

January 26, 1996

Victor Fratelli, Ph.D.
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street HFS-455
Washington, DC 20204

Dear Dr. Fratelli,

Notice is hereby given pursuant to the requirements to Section 413(a)(2) (21 U.S.C. 350b) of the Federal Food, Drug and Cosmetic Act of two new dietary ingredients which will be introduced in the dietary supplement Dormialfin. These new dietary ingredients have a long history of safe use in Mexico, and published articles support the conclusion that these ingredients are safe in expected use.

The new dietary ingredients, and citations to published articles supporting their safety, are:

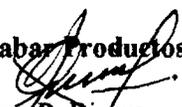
White Sapote (scientific name *Casimiroa edulis*, Mexican name Zapote blanco)
M. Martinez, Las Plantas Medicinales de México (1944), Zapote blanco, pp. 349-355.
J.F. Morton, The Drug Aspects of the White Sapotes (1962), Economic Botany Vol.16, pp. 288-294.

Tepozan (scientific name *Buddleja americana*, Mexican name Tepozan)
M. Martinez, Las Plantas Medicinales de México (1944), Tepozan, pp. 309-316.
P.J. Houghton, Ethnopharmacology of Some Buddleja Species (1984), J. Ethnopharmacol. vol. 11, pp. 293-308.

Copies of the four articles are enclosed, along with English translations (made by an expert translator) of the two articles originally in Spanish.

These new dietary ingredients will not be marketed in the US for 75 days after your expected receipt of this notice.

Very truly yours,

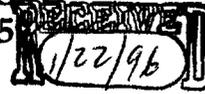

Malabar Productos Naturales S.A. De C.V.

Norma P. Rivera
Export Manager

44428



Tinos L. L. C.
2500 Brownsboro Road
Louisville, KY 40206 U.S.A.
Phone/Fax (502) 896-4151



January 18, 1996

Robert J. Moore, Ph.D.
Senior Regulatory Scientist
Division of Programs and Enforcement Policy
Office of Special Nutritionals
U.S. Food and Drug Administration
200 "C" Street. S.W.
Washington, D.C. 20204

RE: Pre-Market Approval of a New Herbal Dietary Supplement

Dear Dr. Moore:

It was a pleasure talking with you on Tuesday, January 16, 1996. I really appreciate you helping me out with all these regulatory affairs.

As per our conversation, I am enclosing journal articles which pertain to the safety as well as substantiation of the claims of a new dietary supplement we intend to market in the U.S. After an exhaustive review of the literature extending over the past year, we believe we have discovered a compound in the dietary food supply which possesses craving suppressant activity. This chemical, called theobromine, is very well known for decades, and is commonly consumed in a myriad of chocolate containing foods. Furthermore, theobromine is generally recognized as safe in the field. It has not been marketed in the U.S. simply because it was felt to have little, if any, activity.

If you have any concerns or issues regarding the marketing of theobromine as a dietary supplement, please let me know. I can be reached anytime by my digital pager (502) 421-9384.

Thank you very much. With best regards,

Sincerely yours,

George A. Kargas, M.D.
George A. Kargas, M.D.
President
TINOS, L.L.C.

VICTOR FRATELLI, PH.D.

Office of Special Nutritionals.

*Center for Food Safety And Applied
Nutrition.*

Food and Drug Administration.

INDEX

I.- The Drug Aspects of White Sapotes
J.F. Morton.

II.- Ethnopharmacology of Some
Buddleja Species.
P.J. Houghton.

III.- Las Plantas Medicinales de México
M. Martínez.

a) Zapote Blanco pp. 349-355.

b) Tepozán pp. 309-316.

IV.-***TRANSLATION.***

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FOOD AND DRUG ADMINISTRATION
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