



Memorandum

Date NOV 13 1996 1209 '96 NOV 18 A11:57
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, HFS-305

New Dietary Ingredient: Extract from the Bark of the Pao Pereira tree
Latin name - Geissospermum vellosii
(Trade name of "Pao V")
Firm: VIVA (USA), Inc.
Date Received by FDA: September 11, 1996
90-Day Date: December 10, 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 ingredient should be placed on public display in docket number 95S-0316 after
December 10, 1996.

Sincerely yours,

James Tanner, Ph.D.
Acting Director,
Division of Programs and
Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Attachment

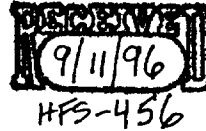
95S-0316

RPT 5

VIVA (USA), Inc.

444 Madison Avenue, Suite 701
New York, NY 10022

Tel : (212) 752-6700
Fax : (212) 319-7584



August 30, 1996

Director of Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety & Applied Nutrition
HFS-455
Food and Drug Administration
200 C Street, SW
Washington, D.C. 20204

Attention: Ms. Peggy Binzer

Re: Notification to the Secretary of Health and Human Services pursuant to Section 8(a)(2) of the Dietary Supplement Health and Education Act of October 25, 1994 (21 USC: Federal Food, Drug and Cosmetic Act)

Dear Ms. Binzer:

VIVA (USA), Inc. ("VIVA") is a corporation incorporated pursuant to the laws of the State of New York. The purposes of VIVA are to research, manufacture and distribute organic health care products.

We hereby present to you information regarding an extract from the bark of the Pao Pereira tree, a new Dietary Ingredient that we would intend to market as a Dietary Supplement in the United States under the name of "Pao V".

Pao Pereira, whose Latin name is *Geissospermum Vellozii*, is a tropical tree native to Brazil, which, in various forms, is traditionally used in that country as a tonic and febrifuge. Pao Pereira extract has been used in Brazil for several centuries and, as a result, has been registered in the Brazilian Pharmacopoeia since 1926.

Pao V is a safe product, as shown by the toxicology study performed by SIR International, a French research institute, a copy of which is enclosed herein for your review, and improves the nutritional value of its consumer's diet. As clinical research has demonstrated, nutritional supplements can promote good health and prevent disease, thereby mitigating the need for expensive medical procedures. Consequently, we feel that the American public shall benefit from the marketing of Pao V.

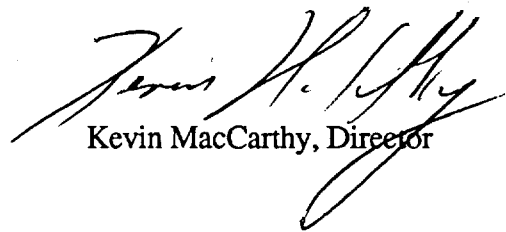
We forward to you herewith the Pao V information file in order to provide your office with documentation evidencing the fact that Pao V is safe for human consumption.

It is our understanding that upon the expiration of seventy six (76) days following your office's receipt of this notification and, absent any responsive commentary from your office, VIVA will be able to market Pao V in the United States.

Upon receipt of this letter we would appreciate it if you could forward to the undersigned an acknowledgment of same.

Should you have any questions or comments regarding the enclosed Pao V information file, please do not hesitate to contact us.

Very truly yours,



Kevin MacCarthy, Director

Encls.