DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: JUN 25 2004

9327 '04 AUG -4 P1:29

From: Division of Dietary Supplement Programs , Office of Nutritional Products, Labeling and Dietary Supplements, HFS-810

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

Subject of the Notification: Hoodia gordonii Powder

Firm: Awarness Corporation

Date Received by FDA: March 29, 2004

90-Day Date: June 27, 2004

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

Tanya D. Jackson Ph.D

95S-0316

RPT 238

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

JUN 10 2004

Susan D. Brienza
Patton Boggs LLP
1660 Lincoln Street, Suite 1900
Denver, CO 80264

Dear Ms. Brienza:

This is to inform you that the notification you submitted, dated March 26, 2004, on behalf of your client, Awareness Corporation, pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on March 29, 2004. Your notification concerns the substance called "*Hoodia gordonii* powder" that you describe as dehydrated plant material of *Hoodia gordonii* (Masson) Sweet ex Decne. that you intend to market as a new dietary ingredient in a multi-ingredient dietary supplement.

According to the notification, Awarness Corporation intends to sell a multi-ingredient dietary supplement of which "*Hoodia gordonii* powder" will be a component. Although you do not describe the other major ingredients in the multi-ingredient dietary supplement or the amount of these ingredients in the supplement, you state that 300 mg per serving of the "*Hoodia gordonii* powder" should be consumed twice daily for a total recommended intake of 600 mg daily. You state that the product label will contain three cautions, prominently printed in bold type: "Not for children under 18. Do not exceed recommended serving size. Do not use if you are pregnant or lactating."

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

FDA has carefully considered the information in your submission, and the agency has concerns about the evidence on which you rely to support your conclusion that a dietary supplement containing "*Hoodia gordonii* powder" will reasonably be expected to be safe.

Your notification references studies that state that there were no reports of any adverse events in a clinical study conducted by Phytopharm. You also stated in your notification that you were unable to acquire a copy of the article documenting this study. In accordance with 21 CFR 190.6(b)(4), any references or citations to published information offered in support of the notification shall be accompanied by reprints or photostatic copies of such references. Further, no conclusions can be drawn from the brief summary statements and references to the unpublished studies. Information such as the investigator(s) name(s), credentials, affiliations, location and date when the unpublished studies were conducted and complete study reports are needed. Since the notification did not include a reprint or photostatic copy of the Phytopharm clinical study, it was impossible for FDA to make a safety evaluation regarding the "*Hoodia gordonii* powder" product.

In addition, the relationship between the composition of the materials used in the various test reports and the composition of the substance you call "*Hoodia gordonii* powder" is unclear. For example, Awareness states that the "*Hoodia gordonii* powder" is dried plant material, but does not provide specifications of purity and limits on potential contaminants or a compositional analysis of your product. There is no information provided in the notification regarding the other components that will be included with the "*Hoodia gordonii* powder" in the multi-component dietary supplement. Therefore, it is not evident that the test substances used in the referenced studies are qualitatively or quantitatively similar to your new dietary ingredient, "*Hoodia gordonii* powder", or how these studies are relevant to evaluating the safe use of your ingredient under the recommended conditions of use.

Furthermore, the history of use information that you submitted generally lacks details on the amount, frequency and duration of use and whether the "*Hoodia gordonii*" plant part and preparation used are the same as what you intend to market as a dietary supplement. For example, it is unclear to us how the history of use information you submitted in your notification relates to the *"Hoodia gordonii* powder*"* that you intend to market as a new dietary ingredient. These details would have helped FDA to determine how this information relates to your product.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that your product containing "*Hoodia gordonii* powder", when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your product may be adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Your notification will be kept confidential for 90 days after the filing date of March 29, 2004. After the 90-day date, the notification will be placed on public display at FDA's Division of Docket Management in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter, please contact Victoria Lutwak at (301) 436-2375.

Sincerely yours,

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

PATTON BOGGS LLP
ATTORNEYS AT LAW

1660 Lincoln Street
Suite 1900
Denver, CO 80264
303-830-1776

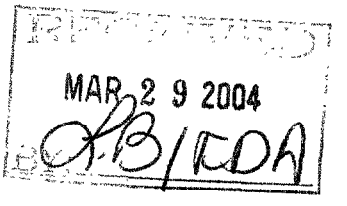
Facsimile 303-894-9239
www.pattonboggs.com

March 23, 2004

Susan D. Brienza
(303) 894-6146
sbrienza@pattonboggs.com

Via Federal Express

Ms. Victoria Lutwak and
Ms. Felicia Satchell
Food and Drug Administration
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park, MD 20740-3835



NDI Notification for Hoodia Gordonii

Dear Ms. Lutwak and Ms. Satchell:

Enclosed you will find the original and one copy of an New Dietary Ingredient Notification for the ingredient Hoodia Gordonii. I am filing this on behalf of our client, Awareness Corporation, a dietary supplement company located in Chandler, Arizona. This Notification is being filed pursuant to Section 8 of the Dietary Supplement Health and Education Act, and 21 C.F.R. sec. 190.6, given that (from our extensive research) Hoodia gordonii appears to be a new dietary ingredient. Also, pursuant to that regulation, you will find attached to this NDI Notification, copies of all of the articles and reports cited therein.

Please notify me of the receipt of this Notification, by your office, at the address above. If you should have any questions about this submission, please contact me at 303-894-6146, or at sbrienza@pattonboggs.com. Thank you in advance.

Sincerely,

Susan D. Brienza

SDB:sdb
Enclosures

cc: Mr. Mark Tahiliani

87848

PATTON BOGGS LLP
ATTORNEYS AT LAW

1660 Lincoln Street
Suite 1900
Denver, CO 80264
303 830-1776

Facsimile 303-894-9239
www.pattonboggs.com

March 26, 2004

Susan D. Brienza
(303) 894-6146
sbrienza@pattonboggs.com

Via Federal Express and E-mail

Ms. Vickey Lutwak
Food and Drug Administration
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park, MD 20740-3835

Re: Full Taxonomy for Hoodia Gordonii

Dear Ms. Lutwak:

As a follow-up to our telephone conversation of today, I am sending you the full taxonomy for Hoodia Gordonii, the subject of our recently-filed New Dietary Ingredient Notification.

Taxonomy: *Hoodia gordonii* (Masson) Sweet ex Decne.

Source: USDA, ARS, National Genetic Resources Program. *Germplasm Resources Information Network* – (GRIN) [Online Database].

I appreciate your calling my attention to this needed detail, and your suggestion to simply add this technical piece of information to the NDI Notification as filed. I am including two copies of this letter, so that one copy may be attached to each of the two copies of the Notification itself, and this letter may be attached to the original of the Notification.

If there is any further information needed, or any other question, please contact me, either by phone or e-mail: at 303-894-6146, or at sbrienza@pattonboggs.com. Thank you for your assistance.

Sincerely,

Susan D. Brienza

SDB:sdb
cc: Mark Tahiliani

87848

additional information to original 75-D PMN

PATTON BOGGS LLP
ATTORNEYS AT LAW

MAR 29 2004

1660 Lincoln Street
Suite 1900
Denver, CO 80264
303-830-1776

Facsimile 303-894-9239
www.pattonboggs.com

March 26, 2004

Susan D. Brienza
(303) 894-6146
sbrienza@pattonboggs.com

Via Federal Express and E-mail

Ms. Vickey Lutwak
Food and Drug Administration
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
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Sincerely,

Susan D. Brienza

SDB:sdb
cc: Mark Tahiliani