



Memorandum

SEP 04 2002

Date:
From: Director, Division of Standards and Labeling Regulations, Office of Nutritional Products, Labeling and Dietary Supplements, HFS-820
Subject: 75-Day Premarket Notification of New Dietary Ingredients
To: Dockets Management Branch, HFA-305

New Dietary Ingredient: Warburgia
Firm: Power Africa, Inc.
Date Received by FDA: November 27, 2001
90-Day Date: February 25, 2002

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 new dietary ingredient should be placed on public display in docket number 95S-0316 as soon as possible since it is past the 90-day date. Thank you for your assistance.

Felicia B. Satchell
Felicia B. Satchell

Attachments

95S-0316

RPT109



FEB 8 2002

Ms. Fedra Sembiante
Power Africa, Inc.
P.O. Box 57
Fairview, NJ 07022

Dear Ms. Sembiante:

This is in response to your correspondence, dated November 21, 2001, to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 350b(a)(2). On November 27, 2001, FDA received and filed four separate notifications, each concerning a different botanical that you assert is a new dietary ingredient. The botanicals are listed below as stated in your notifications, with the exception that we italicized the Latin binomial names and capitalized the genus names.

- African Ginger [*Siphonochilus aethiopicus* (Schweinf.) B.L. Burt]
- African Potato [*Hypoxis hemerocallidea* (Fisch. & C.A.) Mey]
- Sutherlandia [*Sutherlandia frutescens* R. Br. subsp. *microphylla* (Burch. Ex DC.) Moshe & Van Wyk ined.]
- Warburgia [*Warburgia salutaris* (Bertol. f.) Chiov.]

In follow up, we contacted you by phone to request further clarification on the identity of Africa Potato and Sutherlandia. On January 20, 31 and February 7, 2002, you responded by facsimile with information that revises the Latin binomial names (including authors' names) for the two botanicals as indicated below, with the exception that we italicized the Latin binomial names:

- African Potato [*Hypoxis hemerocallidea* Fisch. & C.A. Mey.]
- Sutherlandia [*Sutherlandia frutescens* (L.) R. Br. or *Sutherlandia microphyllia* Burchell ex DC.]

Your notifications describe the plant part, amount and frequency of use for each of the botanicals you intend to market as a dietary supplement as follows:

- African Ginger: roots and rhizomes; no chemical extraction—100% pure plant; 100 mg/capsule or tablet; 1 capsule or tablet 3 times/day with meals

- African Potato: corm, no chemical extraction--100% pure plant; 300 mg/capsule or tablet; 2 capsules or tablets/day
- Sutherlandia: leaves and young stems, no chemical extraction—100% pure plant; 300 mg capsule or tablet; 1 capsule or table twice/day preferably with meals
- Warburgia: leaves, no chemical extraction—100% pure plant; 100 mg/capsule or tablet; 1 capsule or tablet/day preferably with meals

21 U.S.C. 350b(a)(2) requires that a manufacturer or distributor submit certain information to FDA at least 75 days before a new dietary ingredient or a dietary supplement containing it is introduced or delivered for introduction into interstate commerce. This information must include the basis on which the manufacturer or distributor has concluded that the new dietary ingredient or a dietary supplement containing it will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under 21 U.S.C 350b(a)(2), there must be a history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the product's labeling, will reasonably be expected to be safe. If this requirement is not met, the new dietary ingredient or dietary supplement containing it is deemed 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.

You submitted copies of the proposed product labels in your notifications for each of the botanicals you want to market in the U.S. The labels for three of the botanicals include statements about their intended use that represent disease claims. In addition, other information you submitted in support of all four botanicals focuses on recommended uses in the treatment of various diseases. Below are examples of excerpts from your notifications that make disease claims:

- For African Ginger:
 - Proposed label statements:
 - “NATURAL ANTI-INFLAMMATORY”
 - “...may help relieve tension headaches, influenza, sinusitis, sore throats and mild asthma.”
 - Other information in the notification:
 - “...for fever or colds and flu....”
 - “...demonstrated to be...anticandidal.”
 - “...effectively treat the fever of malaria, as well as the severe headache that accompanies the fever.”
 - “...treatment for oral and oesophageal thrush in AIDS patients....”
 - “...oral treatment with African Ginger is effective for vaginal thrush.”

- For African Potato:
Information in the notification:
 - “...it fights AIDS, cancer, TB, yuppie flu, arthritis, psoriasis....”
 - “...Hypoxis plant treatment...seems to slow down the growth of certain types of cancer.”

- For Sutherlandia:
Proposed label statements:
 - “...to help cope with depression and chronic fatigue syndrome.”
 - “...to help treat diabetes, heartburn, gastritis and reflux oesophagitis as well as rheumatism and rheumatoid arthritis.”Other information in the notification:
 - “...contemporary uses of Sutherlandia include use as a tonic for:...wasting from cancer, TB and AIDS...influenza, viral hepatitis, asthma and bronchitis, type 2 diabetes, mild to moderate hypertension, rheumatoid arthritis [and] peptic ulcer, gastritis, and reflux oesophagitis...”
- For Warburgia:
Proposed label statements:
 - “ANTI-MICROBIAL”
 - “...used to help treat yeast, fungal, bacterial and protozoal infections....”
 - “Warburgia may help to treat oral and oesophageal thrush, aphthous ulcers, bronchitis, and is a natural antibiotic particularly for chest infections.”Other information in the notification:
 - “...widely used remedy for coughs, colds and chest complaints.”
 - “The numerous other ailments for which it is used include influenza, rheumatism, malaria, venereal diseases, toothache and gastric ulcers.”
 - “...used to treat yeast, fungal, bacterial and protozoal infections....”

All four product labels include warning statements. These statements advise against the use of these botanicals by children and by pregnant or lactating women. They also advise potential consumers to first consult with a physician if they are using chronic medications or have allergies.

Under 21 U.S.C. 321(g)(1)(B), a drug is defined as an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals. Collectively, the information in your notifications represents each of the four botanicals as a product intended to be used to treat one or more diseases. Therefore, each is subject to regulation as a drug under 21 U.S.C. 321(g)(1)(B) and is not a dietary supplement. If you want African Ginger, African Potato, Sutherlandia or Warburgia to be evaluated for its use in the treatment of a disease, you should contact FDA’s Center for Drug Evaluation and Research, Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

As we have stated above, a product containing African Ginger, African Potato, Sutherlandia, or Warburgia is subject to regulation as a drug. Nonetheless, FDA carefully considered the information in your notifications in the event that these botanicals could be marketed as dietary supplements. We have significant concerns about the basis upon which you concluded that a dietary supplement containing African Ginger, African Potato, Warburgia or Sutherlandia is reasonably expected to be safe when used as recommended or suggested in the products' labeling.

The history of use information in your notifications on the four botanicals addressed use in traditional African medicine to treat specific diseases and other health problems. This information does not discuss the chronic, long-term use of these botanicals as a food or dietary supplement by a generally healthy population. In many instances, the source of your information is not identified (i.e., lacks reference citation), and appears to be selected pages printed from a commercial Internet site or promotional literature that is not scientifically objective. Much of the history of use information you submitted addresses the effectiveness and not "safety" of the botanicals, and is based upon anecdotal or testimonial statements that cannot be validated and are not corroborated by scientific data. In some instances, the information you submitted in your notifications pertains to a different preparation of the botanical than you intend to market. For example, most of the history of use information you submitted on African Potato was on an unspecified extract of this botanical versus the corn (whole plant part and not a chemical extraction) that you propose to use in a dietary supplement.

With few exceptions, the history of use information you submitted in your notifications generally lacks details on the amount, frequency and duration of use for each of the botanicals and whether the plant parts and preparation used are the same as what you intend to market in dietary supplements. Without these details, it is not possible for FDA to determine how this information relates to your botanical products and their recommend intakes.

Your notification on Sutherlandia includes information prepared by Phyto Nova, a distributor of Sutherlandia tablets in South Africa, that states there were no adverse effects reported to Phyto Nova in two years of selling this product. However, you did not provide any particulars on: the method used by Phyto Nova to collect this information; whether Phyto Nova's botanical preparation is identical to the one you want to market; the total daily intake of Sutherlandia or its duration of use; or the number, demographics or health status of the people who used Sutherlandia. Without this clarification, FDA cannot interpret this report as providing credible evidence of safety for your product of Sutherlandia and its recommended intake of 600 mg/day.

Your notifications did not include any scientific data (e.g., results from toxicity, animal studies, *invitro*, *invivo* or clinical studies) that addresses the safety of African Ginger, African Potato, Sutherlandia or Warburgia. Your notifications on African Ginger and Sutherlandia

contained some narratives followed by reference lists, but no copies of the articles cited were included. Therefore, it is unknown whether these reference citations provide any support for your safety determination of these botanicals. With the exception of African Potato, none of the other notifications included copies of articles published in peer-reviewed scientific journals, textbooks, or other authoritative references.

The topics of the two journal articles submitted in your notification on African Potato are on the role or activity of a plant phytosterol called sitosterol and a sitosterol glucoside in human nutrition. Although, African Potato may be a source of these substances, these articles do not provide evidence of safety for African Potato that may contain other bioactive components that affect this botanical's safety profile. The abstract of another published article you submitted in the notification on African Potato assessed the toxicity of a standardized "Hypoxis plant extract." This extract is not the same as the whole plant part of corm that you identified for use in your dietary supplement containing African Potato. In addition, you did not accompany this abstract with a copy of the complete published journal article for FDA's review. Overall, the history of use information you submitted in all four of your notifications has limited usefulness in evaluating the safety of African Ginger, African Potato, Sutherlandia, and Warburgia.

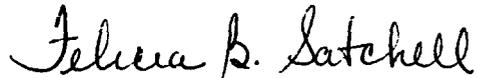
For the reasons discussed above, African Ginger, African Potato, Sutherlandia and Warburgia are subject to regulation as drugs under 21 U.S.C. 321(g)(1)(B), and FDA would consider them to be unapproved new drugs under 21 U.S.C. 355(a). Unapproved new drugs are prohibited under 21 U.S.C. 331(d) from being introduced or delivered for introduction into interstate commerce. Further, if it can be argued that these botanicals may be used as dietary supplements, the information in your notifications does not provide an adequate basis to conclude that African Ginger, African Potato, Sutherlandia or Warburgia will reasonably be expected to be safe when used under the recommended or suggested conditions of use in the products' labeling. Therefore, any product containing African Ginger, African Potato, Sutherlandia or Warburgia may be adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains one or more new dietary ingredients at levels for which there is inadequate information to provide reasonable assurance that they will not present a significant or unreasonable risk of illness or injury. Adulterated or unsafe dietary supplements are prohibited under 21 U.S.C. 331(a) and (v) from being introduced or delivered for introduction into interstate commerce.

Your notifications will be kept confidential for 90 days after the filing date. After February 25, 2002, the four notifications will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. However, any trade secret or otherwise confidential commercial information in the notifications will not be disclosed to the public.

Page 6 – Ms. Fedra Sembiente

For FDA's consideration, you may wish to identify in writing specifically what information in your notifications you believe is proprietary. Nevertheless, our Center's Freedom of Information Officer has the authority to make the final decision about what information in the notifications should be redacted before they are posted at Dockets.

Sincerely yours,



Felicia B. Satchell

Director

Division of Standards

and Labeling Regulations

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

and Applied Nutrition



"Health by Nature"

facsimile transmittal

To: Ms. Rhonda Kane, M.S., R.D. Fax: 301 436 2639 / 436 2636

From: Fedra Sembiante Date: 1/20/2002

Re: Power Africa Pages: One

Urgent For Review Please Comment Please Reply Please Recycle

Dear Ms. Kane,

Further to our recent submittal of four New Dietary Ingredient notifications for Power Africa, please note that although we do have additional information about on-going research, we kindly advise that at this point we do not wish to add to the information already submitted.

We will be sending details of Latin binomial authors in the next few days and are grateful for the opportunity to clarify this aspect of our notifications.

Fedra Sembiante





DEC 21 2001

Mr. Fedra Sembiante
Power Africa, Inc.
P.O. Box 57
Fairview, NJ 07022

Dear Mr. Sembiante:

This is to inform you that the four separate notifications, each dated November 21, 2001, you submitted pursuant to 21 U.S.C. 350b(a)(2) were all received and filed by the Food and Drug Administration (FDA) on November 27, 2001. Collectively, four botanicals were identified in your notifications that you assert are new dietary ingredients. These botanicals are listed below as stated in your notifications, with the exception that we italicized the Latin binomial names and capitalized the genus names:

- African Ginger [*Siphonochilus aethiopicus* (Schweinf.) B.L. Burt]
- African Potato [*Hypoxis hemerocallidea* (Fisch. & C.A.) Mey]
- Sutherlandia [*Sutherlandia frutescens* R.Br. subsp. *microphylla* (Burch. Ex DC.) Moshe & Var. Wyk ined.]
- Warburgia [*Warburgia salutaris* (Bertol. f.) Chiov.]

In accordance with 21 C.F.R § 190.6(c), FDA must acknowledge its receipt of a notification for a new dietary ingredient. For 75 days after the filing date (i.e., February 10, 2002), you must not introduce or deliver for introduction into interstate commerce any dietary supplement that contains one or more of the botanicals cited above.

Please note that our acceptance of your notifications for filing is a procedural matter. It does not imply that we have completed our review of the notifications or constitute a finding by FDA that your proposed new dietary ingredients or a supplement that contains them is safe or is not adulterated under 21 U.S.C. 342.

As another procedural matter, your notifications will be kept confidential for 90 days after the filing date. After February 25, 2002, the four notifications will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. However, any trade secret or otherwise confidential commercial information in the notifications will not be disclosed to the public.

Page 2 – Mr. Fedra Sembiante

For FDA's consideration, you may wish to identify in writing specifically what information in your notifications you believe is proprietary. Nevertheless, our Center's Freedom of Information Officer has the authority to make the final decision about what information in the notifications should be redacted before they are posted at Dockets.

We noticed that none of your notifications included either a phone or facsimile (fax) number or an electronic mail address as other ways to contact you. Although you are not required to provide us with this information, we would appreciate your sharing it with us, if it exists, as quicker ways to communicate with you.

Since the receipt of your notification, we have relocated our office. Our new address and other contact information follows:

Division of Standards and Labeling Regulations (HFS-820)
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740-3835
Phone: (301) 436-2371
Fax: (301) 436-2639 or (301) 436-2636

Thank you for your consideration of our request for additional information on how to reach you. Please contact us, if you have any questions concerning this correspondence.

Sincerely yours,



Rhonda R. Kane, M.S., R.D.
Consumer Safety Officer
Dietary Supplements Team
Division of Standards
and Labeling Regulations
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

RECEIVED

11-27-01

NEW DIETARY INGREDIENT NOTIFICATION

Pre-market notification

November 21, 2001

1) Distributor:

Power Africa, Inc
P.O. Box 57
Fairview, NJ 07022

2) Name of the new dietary ingredient that is the subject of the pre-market notification, including Latin binomial name and author:

Name: Warburgia
Latin binomial: warburgia salutaris
Author: (Bertol. f.) Chiov.

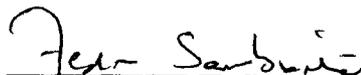
3) Description of dietary supplement:

- i. **level of new dietary ingredient in dietary supplement:**
100mg Warburgia per one capsule/tablet serving of the same quantity. No chemical extraction - 100% pure plant.
- ii. **conditions of use suggested in labeling of dietary supplement:**
one capsule/tablet twice daily preferably with meals (please refer to attached copy of label).

4) History of use, evidence of safety, citations to published articles and additional information that is basis to the distributor's conclusion that the new dietary supplement will be reasonably expected to be safe:

please refer to copies of material attached.

5) Signature of person designated by distributor of dietary supplement that contains a new dietary ingredient:


Fedra Sembiante

Warburgia Salutaris

Presented by Power Africa, Inc.

Distributed by:
Power Africa, Inc. PO Box 57
Trenton, NJ 07122 USA

Power Africa®

"Health by Nature"

Warburgia

(warburgia salutaris)

ANTI-MICROBIAL*



100 mg Dietary
Supplement

60 Capsules

Supplement Facts:	
Serving Size: 1 Capsule	
Each capsule contains	% Daily Value*
Warburgia salutaris	100 mg
*Daily value not established	

Other ingredients: Dicalcium Phosphate Triach, Magnesium Stearate

SUGGESTED USE: As a dietary supplement*, take one (1) capsule twice daily, preferably with meals.

The Warburgia tree is the most valuable of the natural African anti-microbials, and the bark and leaves have been used to help treat yeast, fungal, bacteria and protozoal infections for centuries. Warburgia may help to treat oral and oesophageal thrush, aphthous ulcers, bronchitis, and is a natural antibiotic particularly for chest infections.*

WARNING: As with any dietary supplement, do not use while pregnant or lactating. Consult a physician if on chronic medication or suffer from allergies. Store in a cool dry place. Keep out of reach of children. Do not use if seal under cap is broken or missing.

ITEM # 110102 / EXPIRY DATE / LOT #

Product of South Africa

100% PURE PLANT NO ARTIFICIAL COLORS OR FLAVORS NO PRESERVATIVES OR CHEMICAL SOLVENTS

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any illness or disease. Research is ongoing.

Help/FAQ's	PRODUCT CODE BUILDER - FINAL RESULTS		Tutorial
Helpful Tips			
Industry	Product	Code	
Vit/Min/Prot/Unconv Diet(Human/Animal)	Herbal & Botanicals(other than teas)/ Hum Fd Dietary Suppl 1 Ingr / Soft Gelatin Capsules / Herbals & Botanicals (not Teas), N.E.C.	54 F B H 99	
« Previous	Start Over	Print	

Help/FAQ's	PRODUCT CODE BUILDER - FINAL RESULTS		Tutorial
Helpful Tips			
Industry	Product	Code	
Vit/Min/Prot/Unconv Diet(Human/Animal)	Herbal & Botanicals(other than teas)/ Hum Fd Dietary Suppl 1 Ingr / Prompt Release Tablets / Herbals & Botanicals (not Teas), N.E.C.	54 F B A 99	
« Previous	Start Over		Print

[Help/FAQ's](#)**PRODUCT CODE BUILDER - FINAL RESULTS**[Tutorial](#)**Helpful Tips**

Industry	Product	Code
Vit/Min/Prot/Unconv Diet(Human/Animal)	Herbal & Botanicals(other than teas)/ Hum Fd Dietary Suppl 1 Ingr / Dried - Natural or Artifical / Herbals & Botanicals (not Teas), N.E.C.	54 F B T 99

[« Previous](#)[Start Over](#)[Print](#)



IMPILO

DRUGS (1966) (PTY) LTD

CERTIFICATE OF ANALYSIS

Batch No. : W3241
Product : WARBURGIA CAPSULES
Alternative names : PEPPERBARK TREE LEEF CAPSULES
Packaging : WHITE PVC JARS (60's)
Expiry Date : 04/2003

	SPECIFICATION	METHOD	RESULT
Description	: Transparent capsule/green powder fill.	Visual	Complies
Average mass	: 580 - 620 mg	Balance	612,5 mg
Length	: 21,0 - 22 mm	Verrier	21,60 mm
Disintegration	: NMT 60 mins	USP 24 (Discs)	28 mins
Uniformity of mass	Wts. of NMT 2 capsules (of 20) may deviate from ave. by MT 7,5 % and none by more than 15 %	Balance	Complies

Willem Laas
QA Manager

Impilo Drugs (1966)(Pty) Ltd • Reg No: 66/00021/07

Directors: A.M. Tully B.Soc. Sci. - M.B. Tully B.Pharm. M.P.S. (Managing)

9 Green St. Isithaba, KwaZulu Natal • PO Box 3322, SUNDUMBILI 4491

Tel: (032) 459 1529 • Fax: (032) 459 1423

E-mail: impilodrugs@cybertrade.co.za



IMPILO

DRUGS (1966) (PTY) LTD

CERTIFICATE OF ANALYSIS

Batch No. :3989
Product :WARBURGLA TABLETS
Alternative names :PEPPERBARK TREE LEAF TABLETS
Packaging :WHITE PVC JARS (60's)
Expiry Date :09/2003

	SPECIFICATION	METHOD	RESULT
Description	:Olive green, freckled, aromatic tablets.	Visual	Complies
Diameter	:10,3 mm	Vernier	10,3 mm
Average mass	:480 - 520 mg	Balance	498,6 mg
Thickness	:4,8 - 5,2 mm	Vernier	5,03 mm
Hardness	:2 - 14 kg	Hardness tester	3,8 kg
Friability	:NMT 1 %	USP 24	0,142 %
Disintegration	:NMT 15 mins	USP 24 (Discs)	14 mins
Moisture content	:NMT 10 %	Karl Fischer	6,96 %

Willem Laas
QA Manager

Impilo Drugs (1966)(Pty) Ltd - Reg No: 1966/000027/01

Directors: A.M. Tully B.Soc.Sci - M.B. Tully B.Pharm. M.P.S (Managing)

7 Green St, Isithebe, KwaZulu Natal - P.O. Box 3322 SUNDUMBALI 4491

Tel. (032) 459 1529 - Fax: (032) 459 1423

E-mail: impilodrugs@cybertrac.com



IMPILO

DRUGS (1966) (PTY) LTD

CERTIFICATE OF ANALYSIS

Batch No. :AU 00203
Product :WARBURGIA SALUTARIS POWDER
Alternative names :PEPPERBARK POWDER
Packaging :POLYETHYLENE BAGS
Expiry Date :04/2003

	SPECIFICATION	METHOD	RESULT
Appearance	:Olive green flaky powder	Visual	Complies
Odour	:Characteristic aromatic		Complies
Taste	:Feint characteristic taste		Complies
Plant material	:Leaves		Complies
Processing	:Freeze dried		Complies
Identification	:To comply to standard	UV/Vis	Complies
Loss on drying	:NMT 5 %	Oven @ 100 °C	3,72%
Preservative	:None		
Foreign matter	:NMT 2 %	Visual (BP 1999)	Complies


Willem Laas
QA Manager

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