



4551 '04 JAN -7 21:49

DEC 22 2003

Ms. Anna Tucci
Executive Vice-President
Aboca USA, Inc.
126 South Spokane Street
Suite C
Seattle, Washington 98134

Dear Ms. Tucci:

This is in response to your letters of October 31, 2003 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Aboca USA, Inc. is making the following claim for the product **Echinacea Plus Root & Flowering Top Herbal Supplement**:

“...supports the immune system and helps promote general well-being in cold and flu season.”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to prevent disease (i.e., the common cold and influenza). This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

You also submitted a notification and copy of a label for a product named **Siberian Ginseng Root Herbal Supplement**. This product is misbranded under 21 U.S.C. 343(u) because it purports to be or is represented as ginseng, but it is not an herb or herbal ingredient derived from a plant classified within the genus *Panax*. In the Federal Register of August 28, 2003 (68 FR 51693) FDA amended 21 CFR 101.4(h) to, in part, implement section 10806 of the Farm Security and Rural Investment Act of 2002 (Pub. L. 107-711) (the Farm Bill). Section 10806(b)(1)(A) of the Farm Bill

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limits the use of the term "ginseng" in labeling or advertising for herbs or herbal ingredients to those that are classified within that genus "Panax." Your product does not contain any *Panax* spp. ingredient, but instead contains an extract of *Eleutherococcus senticosus*. Therefore, the use of the term "Siberian ginseng" in the statement of identity, the supplement facts panel, and elsewhere on the label misbrands the product under the Act. The introduction or delivery for introduction into interstate commerce of any food, including a dietary supplement, that is misbranded is prohibited under 21 U.S.C. 331(a) and such a product is subject to enforcement action under the Act.

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "S. Walker", with a long horizontal line extending to the right.

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

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Seattle District Office, Office of Compliance, HFR-PA340

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cc:

all w/copy of incoming

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-800 (file)

HFS-810

HFS-811 (Moore w/original incoming)

HFD-40 (Behrman)

HFS-607

HFV-228 (Benz)

GCF-1 (Nickerson)

f/t:HFS-811:rjm:11/28/03:docname:86250.adv:disc80



Growing Herbs for Health

Office of Special Nutritionals,
Center for Food Safety and Applied Nutrition,
Food and Drug Administration
200 C St. SW.
Washington DC - 20204

RECEIVED
NOV 17 2003
BY:

October 31, 2003

Aboca USA Inc., located at 126 South Spokane Street/Suite C, Seattle – Washington 98134, submits the following notification of marketing in the United States of an herbal supplement imported from Italy. Aboca will sell the product to medical practitioners and qualified retailers in the USA.

NOTIFIES

The marketing of the following Herbal Supplement:

Brand Name: Echinacea Plus Root & Flowering Top Herbal Supplement

Presentation: 1.17 Oz (33.3 g) 90 Capsules in glass bottle

Name and address of the manufacturer: Aboca S.p.a., Via della Liberta' 37/ter – Pistrino di Citema Perugia - Italy

Name and address of the distributor: Aboca USA Inc., 126 South Spokane Street/Suite C, Seattle Washington – 98134 USA

TEXT OF THE STATEMENT: Echinacea Plus supports the immune system and helps promote general well-being in cold and flu season.*

Text of the disclaimer: *This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

HERBAL INGREDIENTS (Amount per serving: 1 Capsule):

- ^ Echinacea purpurea (flowering top) – W.P.C. ** 124 mg
- ^ Echinacea pallida (root) – W.P.C. ** 124 mg
- ^ Echinacea angustifolia (root) – W.P.C. ** 42 mg

OTHER INGREDIENTS: Gelatin (capsule).

21751

^ = Certified organic (EU Directive 2092/91)

****WPC:** "Whole Phytocomplex Concentrate" (W.P.C.) is a combination of freeze dried extract with the powder of the same portion of the plant.

WARNING: Do not take if you are pregnant or nursing. For other contraindications and cautions, please consult your health care practitioner. Keep out of reach of children.

I Anna Tucci, Executive Vice-President and General Manager of Aboca USA, certify that all the information presented and contained in this notice is complete and accurate, and that Aboca USA has substantiation that the statement is truthful and not misleading.



Anna Tucci

Executive Vice-President
Aboca USA

6 times a
with care

per capsule
% Daily Value
1 per capsule
per capsule
of the plant.

nsuring. For
consult your

Aboca:
Growing Herbs for Health

Since 1978, Aboca has grown herbs using organic farming processes. Today Aboca's farmlands occupy over 1700 acres, all certified organic in accordance with EU Directive 2092/91. Our mission is to provide the safest and most effective herbal supplements, by combining the ancient tradition of herbal remedies with the most sophisticated scientific research and production technology. Aboca is committed, from seed development to final packaging, to making the world's most natural herbal products for health needs, without the use of any chemical excipients or additives.

To learn more about Aboca, visit:
www.aboca.us

MADE IN ITALY

The dark glass bottle is amber colored for your protection preserving the product from all moisture and microbial contaminants.

Our box prevents any future exposure to the light, fully ensuring its original stability and potency.

All materials are completely recyclable.

Keep in a dry cool place

ASUSECPJLUPW-A

Best before



Echinacea Plus supports the immune system and helps promote general well-being in cold and flu season.

Echinacea Plus

Herbal Supplement

Root & Flowering Top



Echinacea purpurea, pallida, angustifolia

Whole Phyocomplex Concentrate

Freeze-Dried
Microzoned Plant
Powder

290 mg per capsule

Net Wt 1.17 oz (33.3 g) 90 capsules

The three species of *Echinacea* (*Echinacea purpurea*, *pallida*, and *angustifolia*) are cultivated from Aboca's organic farms, and are combined for strength and efficacy. Systematic quality controls implemented throughout the entire production process and analytical testing performed on raw material and finished product validate the safety and effectiveness of this herbal supplement.

Though echinacoid and polyphenols are considered among the main ingredients of *Echinacea Plus*, many other plant components contribute to the herb's efficacy. That is why Aboca has developed W.P.C. (*Whole Phyocomplex Concentrate*) is a combination of the freeze-dried extract with microzoned powder from the same portion of the plant to assure maximum bioavailability, optimum concentration of active principle and the full-spectrum of constituents.

The result is a product with uniform content of echinacoid and polyphenols without the use of excipients, colorings, flavorings, or preservatives. GMPed free.

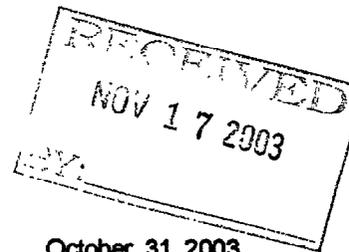
*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Aboca
100% Natural
Manufactured by:
Aboca S.p.A. Via della Libertà 37/riv. - Pesmo di Cilena,
Toscana - Italy
Distributed by:
Accia USA Inc., 126 South Spokane Street, Suite C,
Seattle - Washington 98134 USA



Growing Herbs for Health

**Office of Special Nutritionals,
Center for Food Safety and Applied Nutrition,
Food and Drug Administration
200 C St. SW.
Washington DC - 20204**



October 31, 2003

Aboca USA Inc., located at 126 South Spokane Street/Suite C, Seattle – Washington 98134, submits the following notification of marketing in the United States of an herbal supplement imported from Italy. Aboca will sell the product to medical practitioners and qualified retailers in the USA.

NOTIFIES

The marketing of the following Herbal Supplement:

Brand Name: Siberian Ginseng Root Herbal Supplement

Presentation: 1.00 Oz (28.3 g) 90 Capsules in glass bottle

Name and address of the manufacturer: Aboca S.p.a., Via della Liberta' 37/ter – Pistrino di Citema Perugia - Italy

Name and address of the distributor: Aboca USA Inc., 126 South Spokane Street/Suite C, Seattle Washington – 98134 USA

TEXT OF THE STATEMENT: Siberian Ginseng (*Eleutherococcus senticosus*), also named Eleuthero or Eleutherococcus, promotes physical and mental vitality.*

Text of the disclaimer: *This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

HERBAL INGREDIENTS (Amount per serving: 2 Capsules):

Siberian Ginseng (root) – W.P.C. ** 468 mg

OTHER INGREDIENTS: Gelatin (capsule).

ni 7.50

****WPC:** "Whole Phytoextract Concentrate" (W.P.C.) is a combination of freeze dried extract with the powder of the same portion of the plant.

WARNING: Contraindicated in high blood pressure. Do not take if you are pregnant or nursing. For other contraindications and cautions, please consult your health care practitioner. Keep out of reach of children.

I Anna Tucci, Executive Vice-President and General Manager of Aboca USA, certify that all the information presented and contained in this notice is complete and accurate, and that Aboca USA has substantiation that the statement is truthful and not misleading.



Anna Tucci

Executive Vice-President
Aboca USA



twice a day
health care

Course Per Serving	mg % Daily Value	400
1.61 mg per capsule		
is a combination of		
portion of the plant.		

od pressure. Do
sing. For other
ee consult your

Aboca:
Growing Herbs for Health.

Since 1978, Aboca has grown herbs using organic farming processes. Today Aboca's farmlands occupy over 1700 acres, all certified organic in accordance with EU Directive 2082/81. Our mission is to provide the safest and most effective herbal supplements, by combining the ancient tradition of herbal remedies with the most sophisticated scientific research and production technology. Aboca is committed, from seed development to final packaging, to making the world's most natural herbal products for health needs, without the use of any chemical excipients or additives.

MADE IN ITALY

The dark glass bottle is nitrogen flushed for your protection. *preserving the product from air, moisture and microbial contamination.* *Clear box prevents any further exposure to the light. Always store in its original sealed and packed.* *Keep in a dry cool place.*

Herbal Supplement

Siberian Ginseng

Root



Eiutherococcus senticosus

Whole PhytoComplex Concentrate

Freeze-Dried
Microized Plant
Extract

234 mg per capsule

100% Natural



Siberian Ginseng (*Eiutherococcus senticosus*), also named *Eiuthero* or *Eiutherococcus*, promotes physical and mental vitality.

This plant is carefully selected by Aboca adhering to the strictest protocols. Systematic quality controls implemented throughout the entire production process and analytical testing performed on raw material and finished product verify the safety and effectiveness of this herbal supplement.

Though *eleuthero*sides B+E are considered among the main ingredients of *Siberian Ginseng*, many other plant components contribute to the herb's exclusive W.P.C. (*Whole PhytoComplex Concentrate*) is a combination of the freeze-dried extract with microized powder from the same portion of the plant, to assure maximum bioavailability, optimum concentration of active principle and the full-spectrum of constituents.

The result is a product with uniform content of *eleuthero*sides B+E without the use of excipients, colorings, flavorings, or preservatives. GMO free.

This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Manufactured by:
Aboca S.p.A. Via della Libera Strada - Piasino di Olegna,
Ferrara - Italy
Distributed by:
Aboca USA Inc. 128 South Spokane Street Suite C,
Seattle - Washington - 98134 USA

ASUSELEUTOPWA

Best before
Batch No.:

