



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

7333 03 NOV -3 11:25

OCT 15 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 letter to the Food and Drug Administration (FDA), dated September 24, 2003, 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 claims, among others, for the products **Planta Medica - Propol Pure Oral Throat Spray** and **Planta Medica - Propol Pure Chewable Throat Lozenges**:

"Provides Instant Soothing Relief for Dry, Scratchy, Sore Throat*;"
"Natural Defense Oral Throat Spray*." (For the spray product only)

The directions for use of the **Propol Pure Oral Throat Spray** state: "Adjust spray nozzle to aim at the affected area. Dispense four sprays per application; repeat throughout the day. For best results, 8 to 10 applications are recommended."

These products do not appear to meet the statutory definition of a dietary supplement contained in 21 U.S.C. 321(ff), and therefore, can not be marketed as dietary supplements. We explain the basis for our opinion below.

The term "dietary supplement" is defined in 21 U.S.C. 321(ff). 21 U.S.C. 321(ff) provides that the term means a product (other than tobacco) intended to supplement the diet that bears or contains a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of the above ingredients. 21 U.S.C. 321(ff) further states that dietary supplements are intended for ingestion in a form described in 21 U.S.C. 350(c)(1)(B)(i) or in compliance with 21 U.S.C. 350(c)(1)(B)(ii), are not represented as conventional food or as a sole item of a meal or the diet, and are labeled as a dietary supplement.

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An article that is delivered orally, but that exerts its effect prior to being swallowed (for example, “Provides Instant Soothing Relief for Dry, Scratchy, Sore Throat” and, in the case of the throat spray product, or that can be directly applied to the affected area without being swallowed and absorbed) is not “intended for ingestion.” As stated above, the definition of dietary supplement in 21 U.S.C. 321(ff) states that a dietary supplement is a product “intended for ingestion.” The term “ingestion” has been addressed by the court in United States v. Ten Cartons, Ener-B Nasal Gel, 888 F. Supp. 381, 393-94 (E.D.N.Y.), aff’d, 72 F.3d 285 (2d Cir. 1995), which states:

The ordinary and plain meaning of the term “ingestion” means to take into the stomach and gastrointestinal tract by means of enteral administration. See Stedman’s Medical Dictionary (4th Lawyer’s Ed. 1976) (defining ingestion as the “introduction of food and drink into the stomach.”); Webster’s Third New International Dictionary (1976) (defining ingestion as “the taking of material (as food) into the digestive system.”)...

The interpretation of the term “ingestion” to mean enteral administration into the stomach and gastrointestinal tract is also supported by the language of the statutory sections immediately preceding and following section 350(c)(1)(B)(ii). Section 350(c)(1)(B)(i) states that the vitamin must be intended for ingestion in tablet, capsule or liquid form. Each of these forms denotes a method of ingestion that involves swallowing into the stomach. Section 350(c)(2) states that a food is intended for ingestion in liquid form under section 350(c)(1)(B)(i) “only if it is formulated in a fluid carrier and is intended for ingestion in daily quantities measured in drops or similar small units of measure.” This elaboration of “liquid form” also denotes ingestion by swallowing the fluid.

Therefore, because the term “ingestion” means introduced into the gastrointestinal tract, products that are intended to have their effect before they are ingested are not subject to regulation as dietary supplements because they are not “intended for ingestion” and are drugs under 21 U.S.C. 321(g)(1)(C) because they are articles (other than food) intended to affect the structure or function of the body.

Planta Medica - Propol Pure Oral Throat Spray and Planta Medica - Propol Pure Chewable Throat Lozenges are both claimed to have “proven naturally antiseptic benefits.” 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 claim that these products or their ingredients impart “antiseptic” properties suggests that these products are intended, in part, to treat, prevent, or mitigate disease, namely, diseases caused by pathogenic microorganisms by killing those microorganisms. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are 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.

Page 3 - Ms. Anna Tucci

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan Walker". The signature is fluid and cursive, with the first name "Susan" written in a larger, more prominent script than the last name "Walker".

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

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, Compliance Branch, HFR-PA340



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**

09T - 8 2003

September 24, 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 a dietary supplement imported from Italy. Aboca will sell the product to medical practitioners and qualified retailers in the USA.

NOTIFIES

The marketing of the following Dietary Supplement:

Brand Name:	Planta Medica – Propol Pure Oral Throat Spray
Presentation:	1.0 Fluid Oz (30 ml)
Name and address of the manufacturer:	Aboca S.p.a., Loc. Aboca 20, I-52037 Sansepolcro - ITALY
Name and address of the distributor:	Aboca USA Inc., 126 South Spokane Street/Suite C, Seattle Washington 98134

TEXT OF THE STATEMENT:

Natural Defense*

100% Pure European Propolis Standardized Extract with ACTIVE flavonoids

Provides Instant Soothing Relief for Dry, Scratchy, Sore Throat*

Natural Defense Oral Throat Spray*

Used for centuries, Bee Propolis has proven naturally antiseptic benefits for your good health.*

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Propol Pure Oral Throat Spray provides the advantages of 100% natural highly concentrated active flavonoids that deliver consistent efficacy you can rely upon with each use...spray after spray.*

The standardized flavonoids in 100% natural Propol Pure Propolis have superior bioavailability that enables your body to more readily derive optimum benefit for your good health.*

This means the purest most effective Propolis extract in every Propol Pure product

Text of the disclaimer:

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

DIETARY INGREDIENTS (Amount per Serving – 4 Sprays):

Propol Pure Throat Spray

Proprietary Blend 380 mg

Propolis Hydroalcoholic extract with Propol Pure (Propolis Dried Extract), Honey, Natural Lemon Flavor, Xanthan Gum, Lemon Essential Oil.

Precautions: Do not take if you are pregnant or nursing. For other contraindications and cautions, please consult your health 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

Propolis Pure
Lemon Flavor
Delicious

Natural Defense Oral Throat Spray

Provides Instant Soothing Relief

Propolis Pure Oral Throat Spray

Used for centuries, Bee Propolis has proven naturally antiseptic benefits for your good health. Propolis Pure Oral Throat Spray contains the finest 100% pure European Propolis extracted by Planta Medica's exclusive process to yield a standardized excipient-free Propolis extract that leaves the highly concentrated active flavonoids intact.

Propolis Pure Oral Throat Spray provides the advantages of 100% natural highly concentrated active flavonoids that deliver consistent efficacy you can rely upon with each use... spray after spray!

Directions for Use: Shake before use. Adjust spray nozzle to aim at the affected area. Dispense 4 sprays per application; repeat throughout the day. For best results, 8 to 10 applications are recommended.

Supplement Facts
Serving size: 4 Sprays
Servings Per Container: 80

Amount Per Serving	% DV
Propolis Pure Throat Spray	
Proprietary Blend 380 mg	†
Propolis Hydromalcolic extract with Propolis Pure (Propolis Dried Extract), Honey, Natural Lemon Flavor, Xanthan Gum, Lemon Essential Oil	
† % Daily Value not established	

The product contains NO artificial sweeteners, colorings, flavorings, preservatives, GMO free

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

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

Propolis Pure

Natural Defense Oral Throat Spray

Planta Medica uses only pure European Propolis, abundant in essential oils to impart a superior content of active flavonoids with a flavorful taste.

Propolis Pure formulates its Propolis with Planta Medica's "Native Extract" technology to produce a highly concentrated Propolis without the use of heat or excipients to render a standardized concentration of active flavonoids. The standardized flavonoids in 100% natural Propolis Pure Propolis have superior bioavailability that enables your body to more readily derive optimum benefit for your good health. This means the purest most effective Propolis extract in every Propolis Pure product.

NEW!
Natural Defense

Propolis Pure

Oral Throat Spray

100% Pure European Propolis Standardized Extract with ACTIVE Flavonoids

Provides Instant Soothing Relief for Dry, Scratchy Sore Throat

Delicious Natural Lemon Flavor



PLANTA MEDICA
European Herbalist Formulas

Since 1978, we have developed quality formulas blending herbs and botanicals to yield healthy benefits for the people of Europe. Planta Medica's combination of the ancient tradition of natural remedies with the most sophisticated scientific research, formulation and production technologies has made Planta Medica the preferred brand of herbal stores throughout Italy. Planta Medica provides you with the purest most effective herbal formulas.


Planta Medica is committed from seed development to final packaging in making the world's most natural standardized herbal products. We are so confident about the reliable quality of our products you have our 100% (money back) satisfaction guaranteed.

Our dedication to your well being and everyday health is your assurance that we deliver consistent function, efficacy and credible performance claims with all our products.

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Best by:
Lot Nu:

Store in a cool dry place
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PLANTA MEDICA

Propolis Pure Oral Throat Spray

Directions for Use: Shake before use. Adjust spray nozzle to aim at the affected area. Dispense 4 sprays per 8 to 10 applications as recommended.

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

Best by:
Lot Nu:

Store in a cool dry place

Manufactured in Italy by Alcea S.p.A. - Italy
Distributed in the USA by Alcea USA Inc., 128 South Spence
St. Louis, MO 63104

Propolis Pure
Oral Throat Spray

100% Pure European Propolis Standardized Extract with ACTIVE Flavonoids

Provides Instant Soothing Relief for Dry, Scratchy Sore Throat

Supplement Facts
Serving size: 4 Sprays
Servings Per Container: 80

Amount Per Serving	% DV
Propolis Pure Throat Spray	
Proprietary Blend 380 mg	†
Propolis Hydromalcolic extract with Propolis Pure (Propolis Dried Extract), Honey, Natural Lemon Flavor, Xanthan Gum, Lemon Essential Oil	
† % Daily Value not established	

The product contains NO artificial sweeteners, colorings, flavorings, preservatives, GMO free

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



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September 24, 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 a dietary supplement imported from Italy. Aboca will sell the product to medical practitioners and qualified retailers in the USA.

NOTIFIES

The marketing of the following Dietary Supplement:

Brand Name: Planta Medica – Propol Pure Chewable Throat Lozenges

Presentation: 1.02 Oz (28.8 g) 40 Lozenges

Name and address of the manufacturer: Aboca S.p.a., Loc. Aboca 20, I-52037 Sansepolcro - ITALY

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

TEXT OF THE STATEMENT:

Natural Defense*

100% Pure European Propolis Standardized Extract with ACTIVE flavonoids

Provides Instant Soothing Relief for Dry, Scratchy, Sore Throat*

Natural Defense Chewable Throat Lozenges*

Used for centuries, Bee Propolis has proven naturally antiseptic benefits for your good health.*

Propol Pure Chewable Throat Lozenges provide the advantages of 100% natural highly concentrated active flavonoids that deliver consistent efficacy you can rely upon with use...lozenge after lozenge*

The standardized flavonoids in 100% natural Propol Pure Propolis have superior bioavailability that enables your body to more readily derive optimum benefit for your good health.*

This means the purest most effective Propolis extract in every Propol Pure product.*

Text of the disclaimer:

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

DIETARY INGREDIENTS (Amount per Serving – 1 Lozenge):

Propol Pure Chewable Lozenge

Proprietary Blend 720 mg

Skim Milk (powdered), Whole Milk (powdered), Cane Sugar, Inuline, Fructose, Orange Juice (Freeze-Dried Extract), Natural Orange Flavor, Propol Pure (Propolis Dried Extract), Natural Lemon Flavor.

Precautions: Do not take if you are pregnant or nursing. For other contraindications and cautions, please consult your health 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

Propol Pure

Natural Defense
Chewable Throat Lozenges*

Delicious
Citrus Flavor

Propol Pure

Propol Pure Chewable
Throat Lozenges[±]

Used for centuries, Bee Propolis has proven naturally antiseptic benefits for your good health.* Propol Pure Chewable Throat Lozenges contain the finest 100% pure European Propolis extracted by Planta Medica's exclusive process to yield a standardized excipient-free Propolis extract that leaves the highly concentrated active flavonoids intact.

Propol Pure Chewable Throat Lozenges provide the advantages of 100% natural highly concentrated active flavonoids that deliver consistent efficacy you can rely upon with use... lozenge after lozenge.*

Directions for Use: Chew lozenge and allow to dissolve in your mouth. Repeat as desired up to a total of 4-6 lozenges daily.

Supplement Facts

Serving size: 1 Lozenge
Servings Per Container: 40

Amount Per Serving	% DV
Propol Pure Chewable Lozenge	
Proprietary Blend 720 mg	†
Skim Milk (powdered), Whole Milk (powdered), Cane Sugar, Inuline, Fructose, Orange Juice (Freeze-Dried Extract), Natural Orange Flavor, Propol Pure (Propolis Dried Extract), Natural Lemon Flavor	

† % Daily Value not established

This product contains NO artificial excipients, colorings, flavorings or preservatives and is GMO free.

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

[±] Lozenges without excipients (USA Registered Patent No. 6207189)

Tamper Proof Blister Pack. Do not use if seal is broken.

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Propol Pure

Natural Defense
Chewable Throat
Lozenges*

Planta Medica uses only pure European Propolis, abundant in essential oils to impart a superior content of active flavonoids with a flavorful taste.

Propol Pure formulates its Propolis with Planta Medica's "Native Extract" technology to produce a highly concentrated Propolis without the use of heat or excipients to render a standardized concentration of active flavonoids.

The standardized flavonoids in 100% natural Propol Pure Propolis have superior bioavailability that enables your body to more readily derive optimum benefit for your good health.* This means the purest most effective Propolis extract in every Propol Pure product.

NEW!
Natural Defense*

Propol Pure

**Chewable
Throat Lozenges**

100% Pure European Propolis
Standardized Extract with ACTIVE Flavonoids

Provides Instant Soothing Relief for
Dry, Scratchy Sore Throat*

Patented Excipient-Free High
Potency Lozenges*

Delicious
Citrus Flavor



PLANTA MEDICA

40 Lozenges Net Wt. 1.12 oz. (31.6 g)

ASUSPROAGCOY-A

Best by:

Lot. Nu:

Store in a cool dry place

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PLANTA MEDICA
European Herbal
Formulas

Since 1974, we have developed quality formulas blending herbs and botanicals to meet healthy benefits for the people of Europe. Planta Medica's combination of the ancient tradition of natural remedies with the most sophisticated scientific research, consultation and production technologies, has made Planta Medica the premier brand of herbal stores throughout Italy. Planta Medica provides you with the purest most effective herbal formulas.

Planta Medica is committed to fine packaging in making the world's most natural standardized herbal products. We are so confident about the reliable quality of our products, you have our 100% (money back) satisfaction guarantee.

Our dedication to your well being and everyday health is your assurance that we deliver consistent function, efficacy and credible performance claims with all our products.

Planta Medica, Inc.
177 Hill Street
New York, NY 10014
Tel: (212) 242-7757