



OCT 15 2002

752 0163

Mr. Ben Safronovitz
Managing Director
Propolis Health Products
35 Hillside Road
Fish-Hoek
Republic of South Africa

Dear Mr. Safronovitz:

This is in response to your letter of September 28, 2002 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 Propolis Health Products (dba Propolis Health Products, USA, 1020 NE 44 Court, Fort Lauderdale, Florida 33334) is making the claim "Nutritional support for increased resistance to colds and flu" for its products **Pro-Kid Propolis & Echinacea Syrup** and **Babee Pro-Kid Propolis & Echinacea Syrup**.

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 these products suggests that they are intended to prevent disease (i.e., the common cold and influenza). These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest 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, 7520 Standish Place, Rockville, Maryland 20855.

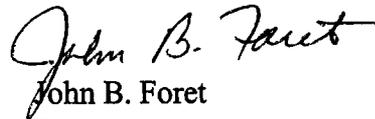
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Page 2 - Mr. Ben Safronovitz

Please contact us if we may be of further assistance.

Sincerely yours,



John B. Foret

Director

Division of Compliance and Enforcement

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, Florida District Office, Office of Compliance, HFR-SE240

PROPOLIS HEALTH PRODUCTS



P.O. BOX 1612, SUNVALLEY 7975

e-MAIL: propolis@icon.co.za
WEBSITE: www.propolishealth.com

CK 2000/046147/23
TEL./FAX: (021) 782-7723
TEL./FAX: (012) 346-8525

**OFFICE OF SPECIAL NUTRITIONALS
(HFS- 450)**

**Center for Food safety and applied Nutrition,
Food and Drug Administration,
200 C St.Sw., Washington, DC 20204
U.S.A**

September 28, 2002

Re: Post Marketing Submission

Dear Sir/ Madam,

Enclose please find the information of the manufacturer
(Herbamed AG of Switzerland) and samples of the
products boxes and labels.

Sincerely Yours,

**Ben Safronovitz
Managing director.
Propolis Health Products.**

...2

Q2119

PROPOLIS HEALTH PRODUCTS



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(2)

Manufacturer particulars:

HERBAMED AG
Untere Au
CH-9055 Buhler
Switzerland
Tel: 41-71-793 30 20
Fax: 41-71-793 37 20

Distributor:

Propolis Health Products cc
35 Hillside Rd,
Fish-Hoek
South Africa.
Tel: 27-21-7827723

The structure/Function statement:

“ Nutritional support for increased resistance to colds and flu “

Ingredient name that is the subject of the statement:

“ Propolis & Echinacea Syrup “

The name of the dietary supplement:

“ Pro-Kid “ & Babee Pro-Kid

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▶ PROPOLIS HEALTH PRODUCTS



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(3)

We hereby certify , that the information contained is complete and accurate.

We hereby as the notifying firm have substantiation that the statement is truthful and not misleading.

A handwritten signature in black ink, appearing to read 'Ben Safronovitz', with a long horizontal stroke extending to the left.

**Ben Safronovitz
Managing Director
Propolis Health Products cc**

**Bobee®
Pro-Kid**

MOM!
you forgot to buy my...
**Bobee®
Pro-Kid**
Nutritional support for increased
resistance to colds and flu*



This package has been sealed for your protection
Do not purchase if ring at base of cap is missing or broken

SUGGESTED DIRECTIONS

If ill or convalescing:
Children under 6: ½ teaspoonful 4 times daily
Children over 6: 1 teaspoonful 4 times daily

Otherwise:
Children under 6: ½ teaspoonful twice daily
Children over 6: 1 teaspoonful twice daily

**Bobee®
Pro-Kid**
Propolis & Echinacea Syrup
Nutritional support for increased
resistance to colds and flu*



SUPPLEMENT FACTS:
Serving Size: 1 teaspoonful
Servings per container: 40

	Amount per %DV Serving
Calories	16.2Kcal †
Sugar	3.95g †
Echinacea Purpurea (Aerial parts)	88.4mg †
Propolis Fluid Extract 1:2	44.2mg †
Rosehip (Cynosbati Fructus)	88.4mg †

Manufactured by
Propolis Health Products, USA
Fort Lauderdale, Florida 33304 USA
© 2003 Propolis Health Products, USA
www.propolishealth.com

SUPPLEMENT FACTS:

Serving Size: 1 teaspoonful
Servings per container: 40

	Amount per Serving	%DV
Calories	16.2Kcal	†
Sugar	3.95g	†
Echinacea Purpurea (Aerial parts)	88.4mg	†
Propolis Fluid Extract 1:2	44.2mg	†
Rosehip (Cynosbati Fructus)	88.4mg	†

† Percent Daily Value not established

Other Ingredients:

Sorbitol
Purified Water
Propyleneglycol
Banana/Apple natural flavoring
Natural coloring

Made in Switzerland by Herboland AG
Imported by Propolis Health Products, USA
1020 NE, 44 Court, Fort Lauderdale, Florida 33304 USA
Toll-Free No.: 1-800-536-6913
www.propolishealth.com e-mail: propolis@propolishealth.com

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SUGGESTED DIRECTIONS

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Children over 6: 1 teaspoonful 4 times daily

Otherwise:

Children under 6: ½ teaspoonful twice daily
Children over 6: 1 teaspoonful twice daily

Consult a physician for use in children under
the age of 6.

A natural fruit flavored syrup, with no artificial
food coloring, especially formulated for
children. Propolis is a natural product from the
beehive.

All extracts are standardized from organically
grown fresh plants and meet the strict
requirements of the Swiss and European
Pharmacopoeias.

* 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.



MOM!
you forgot to buy my...
Pro-Kid
Propolis & Echinacea Syrup

Nutritional support for increased resistance to colds and flu*



Specially formulated for children

This package has been sealed for your protection
Do not purchase if ring at base of cap is missing or broken

SUGGESTED DIRECTIONS

If ill or convalescing:

Children under 6: ½ teaspoonful 4 times daily

Children over 6: 1 teaspoonful 4 times daily

Otherwise:

Children under 6: ½ teaspoonful twice daily

Children over 6: 1 teaspoonful twice daily

Consult a physician for use in children under the age of 12.

A natural fruit flavored syrup, with no artificial food coloring, especially formulated for children. Propolis is a natural product from the beehive.

All extracts are standardized from organically grown fresh plants and meet the strict requirements of the Swiss and European Pharmacopoeias.

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Pro-Kid
Propolis & Echinacea Syrup

Nutritional support for increased resistance to colds and flu*



Natural fruit flavored syrup of Propolis & Echinacea

Specially formulated for children
No artificial food coloring

SUPPLEMENT FACTS:

Serving Size: 1 teaspoonful
Servings per container: 40

	Amount per %DV Serving
Calories	17.2Kcal †
Sugar	4.2g †
Echinacea Purpurea (Aerial parts)	73.7mg †
Propolis Fluid Extract 1:2	73.7mg †
Rosehip (Cynosbati Fructus)	73.7mg †

† Percent Daily Value not established.

Made in Switzerland by Herbamed AG
Imported by Propolis Health Products, USA
1020 NE, 44 Court, Fort Lauderdale, Florida 33304 USA
Tel-Free No.: 1-800-520-2911
www.propolishealth.com e-mail: propolis@propolis.com

SUPPLEMENT FACTS:

Serving Size: 1 teaspoonful
Servings per container: 40

	Amount per Serving	%DV
Calories	17.2Kcal	†
Sugar	4.2g	†
Echinacea Purpurea (Aerial parts)	73.7mg	†
Propolis Fluid Extract 1:2	73.7mg	†
Rosehip (Cynosbati Fructus)	73.7mg	†

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Other Ingredients:

Purified Water
Propyleneglycol
Loganberry Strawberry natural flavoring
Natural coloring

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Imported by Propolis Health Products, USA
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Tel-Free No.: 1-800-520-2911
www.propolishealth.com e-mail: propolis@propolis.com

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