



OCT 15 2002

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.

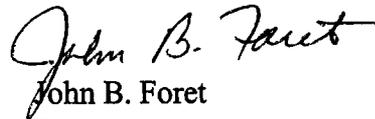
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Page 2 - Mr. Ben Safronovitz

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.**

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Q2119

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TEL./FAX: (012) 346-8525

(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'.

**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  
© 2004 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

**MOM!**  
you forgot to buy my...  
**Bobee®  
Pro-Kid**

**Nutritional support for increased  
resistance to colds and flu\***



This package has been  
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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 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  
Toll-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	†

† Percent Daily Value not established

**Other Ingredients:**

Purified Water  
Propyleneglycol  
Loganberry Strawberry natural flavoring  
Natural coloring

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

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Children under 6:

½ teaspoonful 4 times daily

Children over 6:

1 teaspoonful 4 times daily

*Otherwise:*

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

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