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SEP 18 2006

Ms. Sara A. McGarvey  
Quality Assurance Technician  
Botanical Laboratories, Inc.  
1441 West Smith Road  
Ferndale, Washington 98248

Dear Ms. McGarvey:

This is in response to your letters of August 25, 2006 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 submissions state that Botanical Laboratories, Inc. is making the following claims for the following products:

**Vi Protection Blend**

- “Supports the body’s antiviral capabilities.”
- “Supports the body’s antibacterial capabilities.”
- “Supports the immune system during cold, flu, and allergy season.”

**Echinacea/Astragalus, Echinacea/Eyebright, Echinacea/GoldenRoot Blackberry, Echinacea/GoldenRoot Orange, Nettles & Eyebright, and Sweet Echinacea**

- “Supports immune response to your respiratory infections.”
- “Supports the immune system during cold, flu, and allergy 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 statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate diseases. 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, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

Page 2 - Ms. Sara A. McGarvey

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Vasilios Frankos". The signature is written in a cursive style with a large initial "V".

Vasilios H. Frankos, Ph.D.  
Acting Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

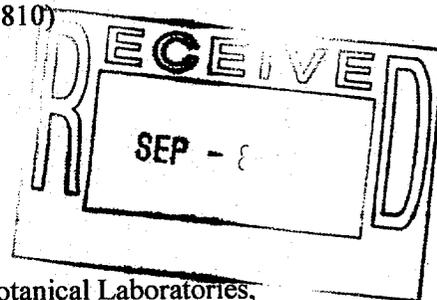
Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, Seattle District Office, Office of Compliance, HFR-PA340



August 25, 2006

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3825



Dear Sir or Madam,

This notification is on behalf of Herbs for Kids® and parent company Botanical Laboratories, Inc., 1441 West Smith Road, Ferndale, WA 98248.

We intend to include the following statements of nutritional support based on substantiated data for the use of Echinacea on the following products.

Ingredient: Echinacea; *Echinacea purpurea* root

Statements: Immune support  
Supports healthy functioning of the immune system  
Supports immune response to your respiratory infections  
Supports the immune system during cold, flu, and allergy season

Product: Echinacea / Astragalus  
Echinacea / Eyebright  
Echinacea / GoldenRoot Blackberry  
Echinacea / GoldenRoot Orange  
Nettles & Eyebright  
Sweet Echinacea

Please be advised that the information contained herein is accurate to the best of our knowledge and information. Our firm has information substantiating that the above statements are truthful and not misleading.

Sincerely yours,

Sara A. McGarvey  
Quality Assurance Technician  
Botanical Laboratories, Inc.

06-7040

#1774

**Botanical**  
**LABORATORIES**  
Helping people live their lives to the fullest

August 25, 2006

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3825

Dear Sir or Madam,

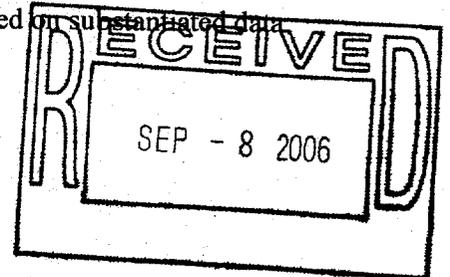
This notification is on behalf of Herbs for Kids<sup>®</sup> and parent company Botanical Laboratories, Inc., 1441 West Smith Road, Ferndale, WA 98248.

We intend to include the following statements of nutritional support based on substantiated data for the use of Echinacea on the following products.

Ingredient: Echinacea; *Echinacea purpurea* root

Statements: Immune Support  
Supports the body's antiviral capabilities  
Supports the body's antibacterial capabilities  
Supports healthy functioning of the immune system  
Supports the immune system during cold, flu, and allergy season

Product: Vi Protection Blend



Please be advised that the information contained herein is accurate to the best of our knowledge and information. Our firm has information substantiating that the above statements are truthful and not misleading.

Sincerely yours,

Sara A. McGarvey  
Quality Assurance Technician  
Botanical Laboratories, Inc.

2006-7044  
AIMS