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Mr. Wayne Reilly
Research manager
Medi Herb Pty., Ltd.
124 McEvoy Street
PO Box 713
Warwick 4370
Queensland, Australia

Dear Mr. Reilly:

This is in response to your letters of January 31, 2001 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 Medi Herb Pty., Ltd. is making the following claims, among others, for the product **Horsetail 1:2**:

“Support the normal clotting function of blood.”

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 treat, prevent, cure or mitigate disease. 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, 7520 Standish Place, Rockville, Maryland 20855.

Your submission also states that Medi Herb Pty., Ltd. is marketing the product “Echinacea purpurea 1:2” as a dietary supplement. This product does 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 a dietary supplement. We explain the basis for our opinion below.

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Page 2 - Mr. Wayne Reilly

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 dietary, and are labeled as a dietary supplement.

This product 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, a product that is used to "make the mouth feel fresh when used as a gargle in an oral hygiene regimen" is not subject to regulation as a dietary supplement because it is not "intended for ingestion."

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Please contact us if we may be of further assistance.

Sincerely,

John B. Foret, Ph.D.
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, San Francisco District Office, Office of Compliance, HFR-PA140

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-811 (r/f, file)

HFD-40 (Behrman)

HFD-310

HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

GCF-1 (Nickerson)

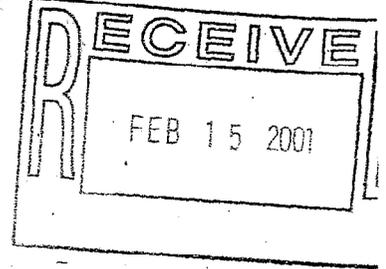
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MEDI HERB

PTY LTD

ACN 006 454 717

PO Box-713 Warwick 4370, Queensland, Australia. 124 McEvoy Street, Warwick.
Reception Tel: 07 46610700 · Orders Tel: 1800 639 122 Fax: 07 46610788
International: +61 7 46610700 International: +61 7 46610788



31 January 2001

The Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200C. Street S.W.
Washington, DC 20204
USA

Dear Sir/Madam

This is a notification pursuant to 21 U.S.C. 343(r)(6) that MediHerb of Warwick, Qld, 4370, Australia is making statements about a dietary supplement.

Horsetail 1:2 is the name of the product that is the subject of this notification.

Horsetail 1:2 contains the herb Horsetail. The statements being made are as follows:

- support and maintain cellular integrity
- promote healthy skin and connective tissue
- encourage healthy urinary tract function
- help support healthy fluid levels, and
- support the normal clotting function of blood.

The information contained herein is accurate and MediHerb has substantiation that the statements are truthful and not misleading.

Yours sincerely

A handwritten signature in cursive script that reads "Wayne Reilly".

Wayne Reilly
Research Manager

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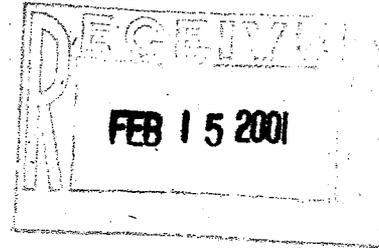
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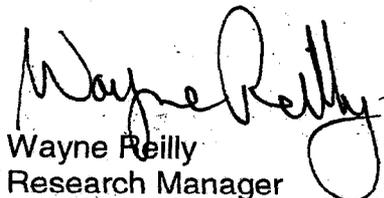
Echinacea purpurea 1:2 is the name of the product that is the subject of this notification.

Echinacea purpurea 1:2 contains the herb Echinacea purpurea. The statements being made are as follows:

- enhance immune system function
- support the tissue cleansing activity of the lymphatic system
- support normal white blood cell activity
- support normal response to environmental stresses
- make the mouth feel fresh when used as a gargle in an oral hygiene regimen
- promote healthy lung function, and
- support healthy upper respiratory tissue.

The information contained herein is accurate and MediHerb has substantiation that the statements are truthful and not misleading.

Yours sincerely


Wayne Reilly
Research Manager

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