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JUN 16 2006

John A. Sichel, RPh, PD
President
Pure Research Products LLC
6107 Chelsea Manor Court
Boulder, Colorado 80301

Dear Dr. Sichel:

This is in response to your letter of June 7, 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 submission stated that Pure Research Products, LLC is promoting the product "Delpro™ Capsules using the following claims, among others, in what appears to be a promotional brochure for the product.

In the section entitled "The potential benefits of Delpro™ Capsules, a dietary supplement:"

"When a virus or bacteria attack us the immune system starts to respond by increasing the level of certain enzymes called lysozymes....The enzymes work to digest the cell wall of the lactobacillus in the intestine to create cell wall pieces or what we call cell wall fragments."

"The newly created cell wall fragments then launch the work of the immune system...."

"The result is the production of phagocytes, the white cells that actually eat up foreign invaders, the NK or natural killer cells that are the primary killers for viruses, the T cells that act like an infantry unit to kill the enemy on the frontlines and B cells that are like the artillery because they fire round after round of antibodies toward the foreign invaders."

"The active biochemical substances found in the cell wall fragments of Del-Immune V create the same natural process in the immune system, described above, when in the presence of foreign substances."

"One of the most common uses for probiotic cultures is for counteracting the diarrhea associated with antibiotic therapy."

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In the section entitled "Our Probiotic Culture Blend:"

"This improved function may be the result of...increased competition with harmful bacteria for docking sites...and the establishment of normal or helpful bacteria during times of antibiotic therapy...."

In the section entitled "Uses:"

"As a dietary supplement to address:

Antibiotic -associated diarrhea acute and chronic diarrhea of any origin.
Chronic Intestinal Infections/Intestinal Dysbiosis; Small Intestinal Bowel Overgrowth (SIBO).
Chemotherapy-associated gastrointestinal side-effects.
Inflammatory Bowel disease Leaky Gut Syndrome (Allergies, Asthma, Epilepsy, Inflammatory Conditions)."

In the section entitled "Nutritional Supplement Strategy:"

"Eliminate pathogenic micro-organisms from bowel microflora ecology."

Other sections (i.e., "Immune System and Anti-Microbial Effects," "Gastro-Intestinal Effects," "Allergies and Antibiotics," "Antibiotics and Probiotics," and "Probiotic Safety") also contain implicit and explicit claims that the product and/or its ingredients have antibiotic effects and/or will prevent, treat, mitigate, or cure specific pathogenic diseases or health related conditions.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling¹ 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 this product suggest that it is intended to treat, cure, prevent, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest 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.² If you intend to make claims

¹It is important to note that the Act defines "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." See 21 U.S.C. § 321(m). The test of whether information can be said to accompany an article and thus constitute "labeling" within the meaning of the Act was set forth in Kordel v. United States, 335 U.S. 345, 350 (1948): "one article or thing is accompanied by another when it supplements or explains it, in the manner that a committee report of the Congress accompanies a bill. No physical attachment one to the other is necessary. It is the textual relationship that is significant."

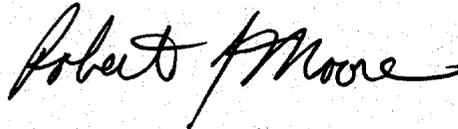
²FDA may, however, also look beyond the labeling of a product to the manner in which the product is advertised or marketed in an effort to determine the product's intended use. See 21 C.F.R. § 201.128.

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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.

Please contact us if we may be of further assistance.

Sincerely yours,



Robert J. Moore, Ph.D.
Team Leader, Compliance and Enforcement
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, Denver District Office, Office of Compliance, HFR-SW240

The intended use of a product may, therefore, be established through product labels and labeling, catalogs, brochures, audio and videotapes, internet sites, or other circumstances surrounding the distribution of the product. If a product is properly defined as a drug in light of such factors, the product is likewise subject to regulation as a drug by FDA.

Pure Research Products LLC

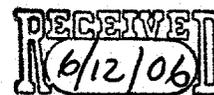
A Division of JA Sichel & Associates, Inc.

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Dr. Robert Moore, Director
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, Maryland 20740



June 7, 2006

Dear Dr. Moore:

Several weeks ago, a call was placed to your office regarding the filing of this label. An administrative person later called and said you were out of the office. In lieu of reaching you by phone, the following is attached.

As required in Title 21, Part 101, Sec 101.93, the label information for Delpro™ Capsules is attached. Delpro™ is a combination of Del-Immune V®, FDA document 95S-0316, and probiotics commonly used in multiple products currently on the market.

Please contact me with any questions or comments.

Respectfully,

A handwritten signature in black ink that reads "John A. Sichel".

John A Sichel, RPh, PD
President
Pure Research Products LLC.
6107 Chelsea Manor Court
Boulder, Colorado 80301

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Pure Research Products LLC

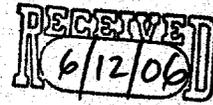
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Respectfully,

A handwritten signature in black ink that reads "John A. Sichel". The signature is written in a cursive style.

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