



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

MAY - 9 2007

2071 7 MAY 23 2007

Mr. John D. Coronite  
Executive Vice President  
Integrated Supplements  
2413 Algonquin Road, Suite 412  
Algonquin, Illinois 60102

Dear Mr. Coronite:

This is in response to your letter of April 23, 2007 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)).

The product **Integrated Supplements Fiber Balance** is the subject of claims that represent that it contains soluble fiber from oat bran that may reduce the risk of coronary heart disease. These statements are not claims subject to 21 U.S.C. 343(r)(6), but claims subject to 21 U.S.C. 343(r)(1)(B) because they represent that the product will reduce the risk of a disease or health related condition (i.e., coronary heart disease). FDA has authorized a health claim about the relationship between soluble fiber from certain foods and coronary heart disease (see 21 CFR 101.81). A dietary supplement that meets the eligibility and message requirements set forth in the regulation may bear a claim for the relationship between soluble fiber and coronary heart disease. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.81 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in 21 CFR 101.81 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, coronary heart disease.

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Please contact us if we may be of further assistance.

Sincerely yours,



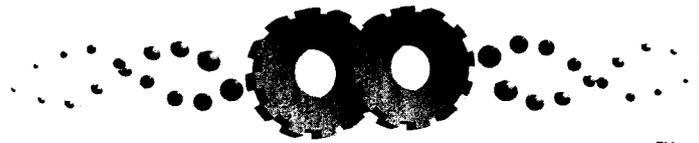
for Vasilios H. Frankos, Ph.D.  
Director  
Division of Dietary Supplement Programs  
Office of Nutrition, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

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, Chicago District Office, Office of Compliance, HFR-CE640



# INTEGRATED<sup>TM</sup> SUPPLEMENTS

2413 Algonquin Road, Suite 412 • Algonquin, IL 60102

Phone: 1.888.605.4216 • Fax: 630.622.1600

www.IntegratedSupplements.com



April 23, 2007

Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-800)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway,  
College Park, MD 20740-3835

Dear Sir or Madam:

Integrated Supplements Inc. hereby wishes to notify the Food And Drug Administration of the intent to distribute and market "Fiber Balance," a dietary supplement whose label shall bear structure/function statements pursuant to Section 403 (r)(6) of the Federal Food, Drug and Cosmetic Act and an authorized health claim pursuant to the Code of Federal Regulations Volume 21 Section 101.14.

The dietary ingredient which is the subject of the structure/function and health claim is Nutrim<sup>®</sup> Oat Bran, a minimally (non-chemically) processed whole oat bran containing 10% beta glucan soluble fiber. (Nutrim<sup>®</sup> is a registered trademark of VDF Futureceuticals, Inc., used under license).

**The statements read as follows:**

**Integrated Supplements Fiber Balance<sup>TM</sup>** is more than just a great digestive aid.\* As part of a healthy diet, it can be useful for maintenance of a healthy body weight,\* and for heart health as well. In fact, soluble fiber from oat bran-containing products such as **Integrated Supplements Fiber Balance<sup>TM</sup>**, as part of a diet low in saturated fat and cholesterol, may lower blood cholesterol and reduce the risk of heart disease. A serving of **Integrated Supplements Fiber Balance<sup>TM</sup>** supplies 0.75 grams of the 3 grams of soluble fiber from oat bran necessary per day to have this effect.

The requisite FDA disclaimer is included, in referece to the asterisks, in boldfaced type, sufficient type size, and displayed immediately below the statement.

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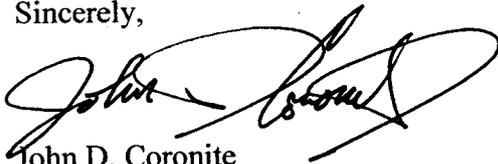
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Integrated Supplements Fiber Balance shall contain levels of Nutrim<sup>®</sup> Oat Bran sufficient to provide 0.75 grams of beta glucan soluble fiber per serving.

Integrated Supplements Fiber Balance shall contain levels of total fat, saturated fat, cholesterol and sodium, in low enough amounts, such as not to disqualify the product from the above health claim.

The undersigned certifies that the information contained in this notice is complete and accurate and that Integrated Supplements possesses substantiation that these statements are truthful and not misleading.

Sincerely,

A handwritten signature in black ink, appearing to read "John D. Coronite", written in a cursive style.

John D. Coronite  
Executive Vice President

Integrated Supplements  
2413 Algonquin Road Suite 412  
Algonquin, IL 60102

Toll Free: 1-888-605-4216