



DEC 22 2006

Pearse Lyons, Ph.D.
President
Alltech Biotechnology Center
3031 Catnip Hill Pike
Nicholasville, Kentucky 40356

Dear Dr. Lyons:

This is in response to your letter of December 5, 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)).

The product **Sel-Plex** is using a claim about selenium and a reduced risk of certain cancers. This statement is not a claim subject to 21 U.S.C. 343(r)(6), but a claim subject to 21 U.S.C. 343(r)(1)(B) because it represents that the product will reduce the risk of a disease or health related condition (i.e., cancer). FDA has issued letters defining the conditions in which it would exercise enforcement discretion with respect to the use of a qualified health claim for dietary supplements containing selenium.¹ A dietary supplement that meets the eligibility and message requirements set forth in the enforcement discretion letters may bear a claim for the relationship between selenium and certain cancers. 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 the relevant enforcement discretion letters 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 the applicable enforcement discretion letters 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, cancer.

97S 0163 LET 919

¹ See letters regarding enforcement discretion with respect to use of qualified health claims about selenium and reduced risk of cancer <http://www.cfsan.fda.gov/~dms/ds-ltr35.html>

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Please contact us if we may be of further assistance.

Sincerely yours,



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, Cincinnati District Office, Office of Compliance, HFR-CE440



December 5, 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 Pkwy
College Park, MD 20740

DEC 15 2006

Re: Notification for Statements of Nutritional Support on Dietary Supplements

Dear Sir/Madam

Alltech, Inc. hereby files notification pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (FDC Act) 21 USC § 343(r)(6).

The certification required by 21 C.F.R. § 101.93(a)(3) is attached.

Brand name:

SEL-PLEX – mineral supplement – capsule

Dietary ingredients:

Selenium yeast, glucose, magnesium stearate, gelatin.

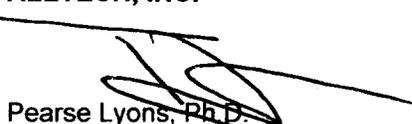
Statement of nutritional support:

Mineral supplement to maintain health.

Selenium may reduce the risk of certain cancers. Some scientific evidence suggests that consumption of selenium may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive.

Selenium may produce anticarcinogenic effects in the body. Some scientific evidence suggests that consumption of selenium may produce anticarcinogenic effects in the body. However, FDA has determined that this evidence is limited and not conclusive.

Sincerely,
ALLTECH, INC.



Pearse Lyons, Ph.D.
President

Attachment: Certification

21 C.F.R. § 101.93(a)(3) certification

I certify that the information contained in the preceding section 403(3)(6) notice for the SEL-PLEX Dietary Supplement is complete and accurate, and that Alltech, Inc. has substantiation that the statements are truthful and not misleading.

Sincerely,
ALLTECH, INC.



Pearce Lyons, Ph.D.
President

December 5, 2006.