



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

1041 01 APR 13 P3:21

MAR 30 2001

Mr. Win Duersch  
Sr. Director of Global Technical Services  
Pharmanex, LLC  
75 West Center  
Provo, Utah 84601

Dear Mr. Duersch:

This is in response to your letter of March 21, 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 Pharmanex, LLC is making the following claim, among others, for the product **LifePak PreNatal**<sup>®</sup>:

“Adequate folate in healthful diets may reduce the risk of having a child with a brain or spinal cord birth defect”  
“... **foli**c acid (400 mcg) may reduce the risk of neural tube defects.”

These statements are not statements of nutritional support subject to 21 U.S.C. 343(r)(6), but are health claims subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between folate and neural tube defects (see 21 CFR 101.79). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between folate and neural tube defects. A health claim for folate and neural tube defects on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.79 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, making a claim that is not in accordance with the requirements in 21 CFR 101.79 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, neural tube defects.

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Page 2 - Mr. Win Duersch

Please contact us if we may be of further assistance.

Sincerely,

*for Robert Moore*  
for John B. Foret

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, Denver District Office, Office of Compliance, HFR-SW240

Page 2 - Mr. Win Duersch

GA-224

HFA-305 (docket 978-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-810 (Foret)

HFS-8 11 (Moore, w/original incoming

HFD-40 (Behrman)

HFD-3 10

HFD-3 14 (Aronson)

HITS-607 (Bayne-Lisby)

HFV-228 (Benz)

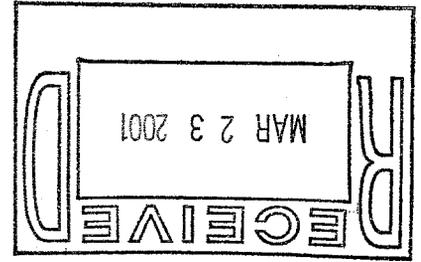
GCF- 1 (Nickerson)

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www.pharmanex.com



By Federal Express

March 21, 2001

Office of Special Nutritional Products Labeling and Dietary Supplements  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration. HFS 8 11  
200 c St. SW  
Washington, DC 20204

RE: Notification for Certain types of Statements on Dietary Supplements

Dear Sir or Madam:

As required by Section 403(r)(6)(c) of the Food, Drug and Cosmetic Act, Pharmanex, LLC, 75 West Center, Provo, Utah 84601, intends to market a dietary supplement product with the following label and marketing statements of nutritional support:

Product identified as LifePak PreNatal® with the following label statements:

- Adequate folate in healthful diets may reduce the risk of having a child with a brain or spinal cord birth defect.
- It provides 650 mg of calcium and 350mg of magnesium daily for proper bone development.
- Delivers comprehensive bone and cardiovascular support.
- Offers superior cell protection against damaging free radical attacks.
- Clinical studies have shown that adequate daily consumption of the B vitamin folic acid (400 mcg) may reduce the risk of neural tube defects.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, LLC has substantiation that these statements are truthful and not misleading.

Sincerely,

Win Duersch  
Sr. Director of Global Technical Services

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