DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**

Food and Drug Administration
5100 Paint Branch Pkwy, HFS-607
College Park, Maryland 20740

APR 12 2006

VITAMIN ARCADE
Unit 2 - 87 Konini Road
Titirangi
Auckland
New Zealand

CFSAN-2006-U-3

Dear Sir:

The Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.storesonline.corn/site/vitaminarcade/and has concluded that claims in your labeling cause your product "Nutramune Plus Nutraferrin (Lactoferrin)" to be a drug as defined in section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 321(g)(1)(B)]. You can find the Act and FDA's regulations through links on FDA's Internet home page: http://www.fda.gov.

Under the Act, articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man are drugs [Section 201 (g)(1)(B) of the Act, 21 U.S.C. 321(g)(1)(B)]. Your web site claims that your product is useful in the prevention and treatment of avian flu and other forms of influenza.

The Internet labeling of your product "Nutramune Plus Nutraferrin (Lactoferrin)" on your web site bears the following claims:

- "Lactoferrin has positive scientific results showing effects to attenuate pneumonia in influenza infections."

- "NutraFerrin
  NutraFerrin is a proprietary trademarked blend of Lactoferrin, from NutraNZ New Zealand NutraFerrin is a versatile, bioactive milk protein which assists the immune system and helps protect the body against Pneumonia from influenza (Bird flu) infections."

- "If there is a Pandemic, then there exists a high probability that you will be exposed. One of the most common ways in which flu kills is through pneumonia in the lungs. Lactoferrin has positive scientific results showing effects to attenuate pneumonia in influenza infections.."

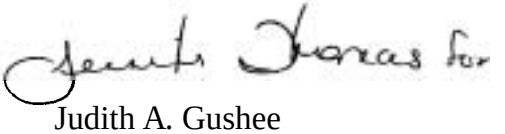
- "Take Nutraferrin to: . . .Prevent . . . flu."

These claims that your product prevents or treats avian flu and other forms of influenza cause your product to be a drug, as defined in section 201(g)(1)(B) of the Act [21 U.S.C. 321(g)(1)(B)]. Because your product is not generally recognized as safe and effective when used as labeled, it is also a new drug as defined in section 201(p) of the Act [21 U.S C. 321(p)]. Under section 505 of the Act [21 U.S.C. 355(a)], a new drug may not be legally marketed in the United States without an approved New Drug Application (NDA).

This letter is not intended to be an all-inclusive review of your web site and products your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

You may respond in writing to Kristen Moe, Compliance Officer, Food and Drug Administration, Division of Compliance and Enforcement, 5100 Paint Branch Parkway, HFS-607, College Park, Maryland 20740-3835. If you have any questions concerning this letter, please contact Ms. Moe at 301-436-2064.

Sincerely,



Judith A. Gushee
Director
Division of Enforcement
Center for Food Safety
and Applied Nutrition