



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

4554
Food and Drug Administration
College Park, MD 20740 7

AUG 21 P5:1

JUL 25 2007

Jarret D. Morrow, M.D.
University Lab Technologies
950 Peninsula Corporate Circle
Suite 3018
Boca Raton, Florida 33487

Dear Dr. Morrow:

This is in response to your letter of June 4, 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)). Your submission states that University Lab Technologies is making the following claims, among others, for the product Arthroleve ULT:

"Provides relief from bone and joint pain."

This claim is a disease claim because it suggests that the product is intended to treat, prevent, or mitigate diseases, namely joint disorders such as arthritis. In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1016-17), FDA stated that "joint pain" is characteristic of arthritis and that it is the most sensitive physical sign of rheumatoid arthritis. For that reason, the agency concluded that claims about relieving joint pain are implied disease claims because they represent that the product will have an affect on a characteristic sign or symptom of a disease (see 21 CFR 101.93(g)(2)(ii)). Moreover, elsewhere in the preamble to the final rule (see 65 FR 1000 at 1030) FDA discussed the circumstances under which claims about pain would imply disease treatment. We stated that since pain is not a normal state, nor are there "normal pain levels," a claim about pain treatment or prevention is ordinarily a disease claim. We addressed the issue of joint pain claims in particular, noting that such claims are disease claims because joint pain is a characteristic symptom of arthritis. We added, however, that a acceptable structure/function claim could be made for pain associated with non-disease states, such as muscle pain following exercise.

19975-0163

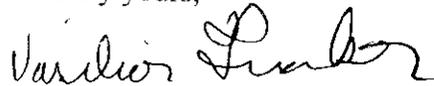
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Page 2 - Dr. Jarret D. Morrow

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests 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. If you intend to make claims 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,



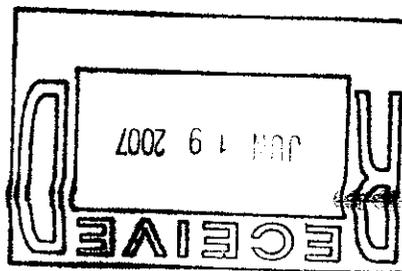
Vasilios H. Frankos, Ph.D.
Director
Division of Dietary Supplement Programs
Office of Nutrition, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

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, Florida District Office, Office of Compliance, HFR-SE240

June 4, 2007

Food and Drug Administration
Office of Special Nutrition (HFS — 450)
Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, DC 20204



Dear Sirs:

Notification is hereby given that University Lab Technologies located at 950 Peninsula Corporate Circle, Suite 3022, Boca Raton, FL, 33487 has marketed dietary supplements bearing the following statement(s) on the label and/or labeling:

Arthroleve ULT

1. Supports cartilage building and repair. *
2. Significantly improves joint function and stiffness. *
3. Provides relief from bone and joint pain. *

Zenstral PMS

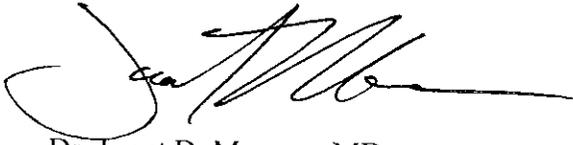
1. PMS related mood disturbances.*
2. Physical symptoms of PMS.*
 - a. Breast tenderness
 - b. Fluid retention
 - c. Cramping

The undersigned certifies that the information contained in this notification is complete and accurate and that University Lab Technologies has substantiation that the statement is truthful and not misleading. Pursuant to 21 C.F.R. § 101.93(a)(1) two copies are enclosed.

2007-4632

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Sincerely,

A handwritten signature in black ink, appearing to read 'Jarret Morrow', with a large, stylized initial 'J' and a long horizontal flourish extending to the right.

Dr. Jarret D. Morrow, MD
President & Chief Scientific Officer
University Lab Technologies