DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

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OCT 17 2003

Mr. Ronald G. Sturtz
President
Lidtke Technologies Corporation
4665 S. Ash Avenue
Suite G-13
Tempe, Arizona 85282

Dear Mr. Sturtz:

This is in response to your letter of September 15, 2003 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 Lidtke Technologies Corporation is making the claims identified below, among others, for the product Joint-EZ.

The label statements you are making describe the use of glucosamine to treat a disease, namely, arthritis (e.g., "Take, for example, the use of glucosamine for the relief of arthritis"). Your label statements state further that research has shown that glucosamine, in combination with chondroitin sulfate, "could reduce the pain and immobility of osteoarthritis." The label goes on to describe your product as a "glucosamine -free answer to good health for your joints." Taken together, the statements being made for your product represent it as an alternative to purported treatments of a disease.

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 statements that you are making for this product suggests that it is intended to treat, prevent, or mitigate a disease (see 21 CFR 101.93(g)), namely, arthritis. It does this by promoting itself as a safe and suitable alternative or replacement for other substances that are described as disease therapies. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest 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.

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Please contact us if we may be of further assistance.

Sincerely yours,

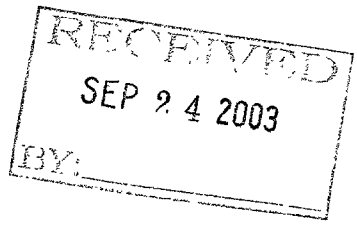
Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, Los Angeles District Office, Office of Compliance, HFR-PA140

LIDTKE
TECHNOLOGIES

FINE QUALITY NUTRIENTS

September 15, 2003



Food and Drug Administration
Office of Nutritional Products
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, DC 20204

Dear Sirs:

Notice is hereby given pursuant to the requirements of section 403(r)(6) (21 U.S.C. 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that Lidtke Technologies Corp., 4665 S. Ash Ave., Suite G-13, Tempe, AZ 85282 has commenced marketing a dietary supplement bearing the following statements on the label and/or in the labeling:

(text of claim on the product label)"Joint-EZ, 'Glucosamine-Free' Joint Support

(text of claim on the product information sheet)"Joint-EZ® – Help Your Joints, Without Hurting Your Health

By Dr. Pat Hallman N.M.D.

Glucosamine-free products are sometimes recommended for individuals with Yeast Overgrowth, Glucose Intolerance, Weight, or Allergy conditions.

How Can Joint-EZ™ Help?

Joint-EZ™ goes beyond supporting the accelerated rebuilding of smooth cartilage and targets your entire connective-tissue system of bone, ligaments and tendons that is necessary to properly convey the mechanical forces exerted by your muscles. Together, the ingredients support the integrity of surrounding tissue, and reduce complications that interfere with healing.

What Have We Learned about Glucosamine?

Illnesses that are either doctor-induced or self-induced are increasing yearly in the United States, with over 1 million cases being reported annually. Not all are the result of negligence, however. Some result from the best of intentions. Take, for example, the use of glucosamine for the relief of arthritis. Early research indicated that certain forms of

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orally-ingested glucosamine, in combination with chondroitin sulfate, could reduce the pain and immobility of osteoarthritis. Bestselling books have been written on this subject. More recently, however, research has confirmed both clinical and anecdotal reports that glucosamine can exacerbate a variety of illnesses. Furthermore, a meta-analysis published in the Journal of the American Medical Association found "large" benefits for chondroitin sulfate but only "moderate" effects for glucosamine.

But Isn't Glucosamine a Component of Connective Tissue?

Glucosamine is a simple amino-sugar made in your cells from fructose 6-phosphate and L-glutamine. Glucosamine is then used as a building block for more complex glycosaminoglycans, including chondroitin sulfate. As such, free glucosamine is not normally found outside the cell. The glucosamine made within your cells is typically sequestered away from the areas where yeast and fungi infect, and its production is tightly monitored and controlled within your cells. In this manner, the glucosamine manufactured by your body follows a far different path from the glucosamine that is taken orally.

Orally ingested glucosamine passes through your digestive tract and into your bloodstream. The yeast that inhabit your digestive tract then feed on glucosamine and incorporate glucosamine into their cell walls. Thus, glucosamine provides yeast with a source of energy as well as the building blocks for overgrowth and a flare-up of symptoms.

Glucosamine and Insulin Resistance

Your body naturally produces glucosamine by way of a sequence of reactions called the hexosamine pathway. This pathway contains a rate-limiting step that controls the intracellular production of glucosamine. Glucosamine that is taken orally, though, enters this pathway downstream of the rate-limiting step, thereby sidestepping cellular controls and flooding your hexosamine pathway. Studies published in both the Journal of Biological Chemistry and Diabetes demonstrate that glucosamine administered in this way can rapidly lower ATP levels and mimic the insulin resistance brought on by elevated levels of glucose and insulin.

Glucosamine Supplements

Although high blood glucose and high insulin levels are known to cause insulin resistance in both skeletal muscle and fat, it is interesting to note that glucose and insulin alone are not enough to produce this effect. They can only produce insulin resistance in the presence of L-Glutamine, a precursor of glucosamine. For this reason, the amino-sugar, glucosamine, is more toxic than the simple combination of glucose and insulin.

Glucosamine supplements are a more serious concern, however, according to the findings of Marshall et al., in that exogenous (administered) glucosamine is forty times more toxic to fat cells than the glucosamine that is produced through your cell's natural hexosamine

pathway. Unfortunately, seniors who are overweight and most prone to insulin resistance are also the population most susceptible to osteoarthritis and are most likely to be using Glucosamine.

Use Joint-EZ to Strengthen Joints and Keep Your Good Health

Order Joint-EZ from Lidtke Technologies and you will receive advanced therapy for joint health, without the damaging effects of glucosamine. If you have a question, Call Lidtke Technologies. We'll put you in touch with a knowledgeable physician who can answer them.

(text of claim on the product advertisement)"It makes you feel like dancing!

Joint-EZ

From the people who care enough to do it right!

Joint-EZ is the glucosamine-free answer to good health for your joints. Glucosamine aggravates candida, increases insulin resistance and only provides "moderate" benefits according to research in the Journal of the American Medical Association (JAMA), you'll find none of it in Joint-EZ.

Joint-EZ:

- Provides "large" benefits, per JAMA
- Strengthens bone, ligaments & tendons
- Speeds smooth cartilage rebuilding
- Supports integrity of surrounding tissue"

Joint-EZ (name of supplement)

Lidtke Technologies Corp. (brand name)

The undersigned certifies that the information contained in this notice is complete and accurate and that Lidtke Technologies Corp. has substantiation that the statement is truthful and not misleading.

Yours truly,

Ronald G. Sturtz
President