



OCT 23 2000

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H. Stephen Brown, Esq.
The Bogatin Law Firm, PLC
1661 International Place Drive
Suite 300
Memphis, Tennessee 38120

Dear Mr. Brown:

This is in response to your letter of October 5, 2000 to the Food and Drug Administration (FDA), on behalf of Cambridge Research Laboratories, Inc., 21 Bridge Square, Westport, CT 06883, 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 Cambridge Research Laboratories, Inc. is making the following claims, among others, for the product **JointEase**:

“...reduce joint discomfort”

“...reduce vascular fragility and subsequent bleeding and bruising, as well as to lower the microtrauma of tissue injuries. It helps limit the tissue destruction associated with injury.”

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 are being made for this product suggest that it is intended to treat, prevent, cure or mitigate. 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, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

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Please contact us if we may be of further assistance.

Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copy:

Mr. Joseph England
President
Cambridge Research Laboratories, Inc.
21 Bridge Square
Westport, Connecticut 06883

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, Nashville District Office, Office of Compliance, HFR-SE340

cc:

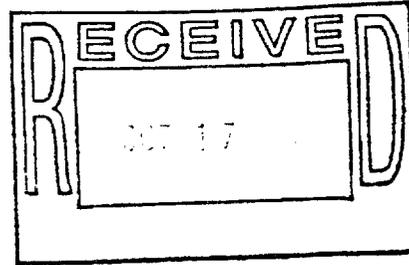
HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-800 (r/f, file)
HFS-810
HFS-811 (file)
HFD-310
HFD-314 (Aronson)
HFS-605
HFV-228 (Benz)
GCF-1 (Dorsey, Nickerson)
f/t:HFS-811:rjm:10/18/00:docname:72937.adv:disc51

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THAD S. RODDA, JR.



October 5, 2000

Dr. Christine Lewis
Officer of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, D.C. 20204

C. MICHAEL ADAMS, JR.
WALTER E. SCHULER
ROBERT Q. WILSON†

‡ Licensed also in Mississippi
▪ Licensed also in Ohio
† Licensed also in Missouri
Y Of Counsel

Re: **JointEase: Notification of Statements of Nutritional Support**

Dear Dr. Lewis:

Enclosed is the original and two copies of an executed Notification of Statement of Nutritional Support as required under Section 101.93 of 21 Code of Federal Regulations and Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, as Amended.

If necessary, please address future correspondence to our firm.

With kindest regards, I am

Very truly yours,

H. Stephen Brown
HSB:cli

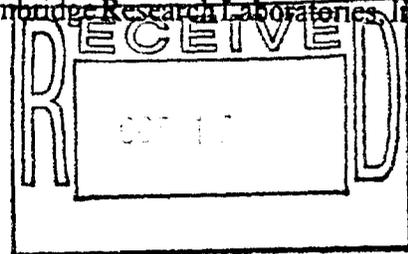
Enclosure(s)

**NOTIFICATION PURSUANT TO
21 U.S.C. §343(r) and 21 CFR §101.93**

Cambridge Research Laboratories, Inc., in accordance with 21 U.S.C. §343(r) and 21 CFR §101.93, hereby submits an original and two copies of its notification within thirty days of first marketing its products with the statements presented below. Cambridge Research Laboratories, Inc., retains scientific documentation supporting the statements.

Name and Address of Distributor:

**Cambridge Research Laboratories, Inc.
21 Bridge Square
Westport, Connecticut 06883**



Supplement Brand Name (ingredients)

JointEase (Glucosamine, cetyl myristoleate (CMO), methylsulfonylmethane (MSM), Vitamin C, tumeric (curcumin), quercitin, manganese)

Text of Statements of Nutritional Support

JointEase offers comprehensive joint function support, building healthy cartilage while maintaining healthy joint tissue.

Designed to help promote and maintain healthy joints, ligaments and tendons.

JointEase supports healthy joint function with the latest scientifically proven constituents to reduce joint discomfort.

JointEase's unique all-natural joint support complex works with the body to nourish the joints from daily wear and tear.

Promotes and supports healthy joints without stomach upset.

Glucosamine is a natural substance found in high concentrations in our joint structures. It is essential in the body's manufacturing cartilage components necessary to maintain the structural integrity of joints and connective tissue.

CMO acts as a natural immuno-modulator, which helps regulate and support a health immune system.

CMO may erase the memory of the badly programmed memory T cells.

MSM has also been attributed with enhancing proper immune cell activity, thereby supporting tissues surrounding the joints.

JointEase's important cartilage matrix constituents are complemented with additional factors for supporting a healthy immune system.

Tumeric helps regulate neutrophil function and scavenge free radicals such as nitric oxide.

Tumeric is a tropical perennial of the ginger family that is native to India. It's most beneficial components are thought to be its volatile oil and various curcuminoids, especially curcumin. The curcuminoids, in studies, have been shown to be potent antioxidants.

Quercetin is a bioflavonoid that works to help keep the capillary blood vessels strong and to reduce vascular fragility and subsequent bleeding and bruising, as well as to lower the microtrauma of tissue injuries. It helps limit the tissue destruction associated with injury.

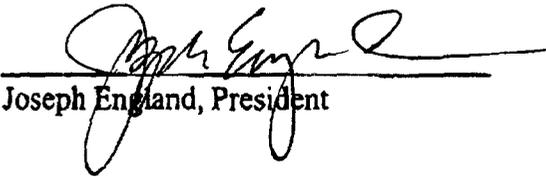
Vitamin C is essential for production of collagen, a protein that gives strength to cartilage.

Magnesium is needed for healthy bone, cartilage, protein, and fatty acid formation, making new cells, activating B vitamins, relaxing muscles, clotting blood, and forming ATP—the energy the body runs on.

In accordance with 21 USC §343(r)(6) and 21 CFR §101.93(c), each of the above statements will be followed by an asterisk that will be cross-referenced to another asterisk on the very same panel or page next to which the following statement will appear in a bold face type: **"These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."**

Respectfully submitted,

Cambridge Research Laboratories, Inc.

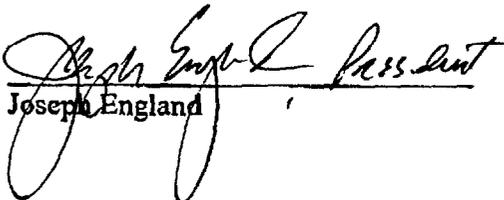
By: 

Joseph England, President

Certification

I, Joseph England, President of Cambridge Research Laboratories, Inc., hereby certify that the information contained in the foregoing notice is complete and accurate and that Cambridge Research Laboratories, Inc., has substantiation that the statements are truthful and not misleading.

Executed: September 28, 2000


Joseph England