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FEB - 8 2001

Mr. Harry August Shippy  
President  
Nutritional Specialties, Inc  
1452 E Katell Avenue  
Anaheim, CA 92805

Dear Mr. Shippy:

This is in response to your letters of January 2, 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 Nutritional Specialties, Inc is making the following claims, among others, for the products below:

**LifeTime® MSM Plus Capsules**

“...reducing joint discomfort...”

**LifeTime® Glucose Control Formula with Glucosol™**

“...a blood sugar lowering substance...”

“...to help control blood glucose levels.”

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 these products suggest that they are intended to treat, prevent, cure, or mitigate diseases, namely, disorders of the joints and in blood glucose regulation. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), including the use of the term “glucose control formula” in the name of the product **LifeTime® Glucose Control Formula with Glucosol™**, and that they are 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.

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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

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-PA240

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-810

HFS-811 (file)

HFD-40 (Behrman)

HFD-310

HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

GCF-1 (Nickerson)

f/t:HFS-811:afp2/1/01:docname:73690:disc1

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January 02, 2001



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Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C St., S.W.  
Washington, DC 20204

RE: Dietary Supplement Statement of Support Notification

To: Whom It May Concern:

Nutritional Specialties, Inc., 1452 E. Katella Ave. Anaheim, CA 92805, the distributor of the following dietary supplement products, intends to make the following statement of support: "LifeTime® MSM Plus is an advanced dietary supplement formula that combines cutting edge natural nutrients that support the body's defense response in (reducing joint discomfort) associated with aging and exercise."

This claim is being made for Cetyl Myristoleate Proprietary Blend (20% CM), MSM (Methyl Sulfonyl Methane), Glucosamine Sulfate, and Type II Collagen. Which is contained in LifeTime® MSM Plus Capsules. This submission is being made in compliance with the requirements of 21 CFR 101.93.

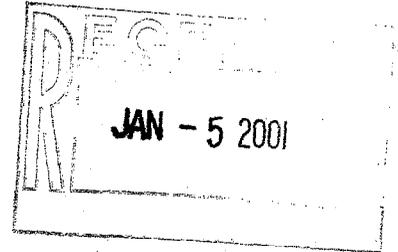
The undersigned is an authorized representative of Nutritional Specialties, Inc. and certifies that the information contained in this notice is complete and accurate, and that Nutritional Specialties, Inc. has substantiation that the above statement is truthful and not misleading.

Harry G. Shippy  
Signature  
HARRY AUGUST SHIPPY  
Full Name  
PRES.  
Title

**NUTRITIONAL SPECIALTIES, INC.**  
1452 E. Katella Ave. • Anaheim, CA 92805  
1-800-333-6168 • 714-634-9340  
FAX: 714-634-9347

January 02, 2001

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C St., S.W.  
Washington, DC 20204



RE: Dietary Supplement Statement of Support Notification

To: Whom It May Concern:

Nutritional Specialties, Inc., 1452 E. Katella Ave. Anaheim, CA 92805, the distributor of the following dietary supplement products, intends to make the following statement of support: "The active constituent in Glucosol™ is corosolic acid, (a blood sugar lowering substance) alpha lipoic acid, chromium (GTF™ Chromium), maitake mushroom, and gymnema sylvestre are all reported to help control blood glucose levels."

This claim is being made for Chromium Picolinate (Patent No. RE 33.988), Glucosol™, Alpha Lipoic Acid, Gymnema Sylvestre (4:1), Maitake Mushroom (Maislin-D)4:1 Extract.

Which is contained in LifeTime® Glucose Control Formula with Glucosol™ Capsules. This submission is being made in compliance with the requirements of 21 CFR 101.93.

The undersigned is an authorized representative of Nutritional Specialties, Inc. and certifies that the information contained in this notice is complete and accurate, and that Nutritional Specialties, Inc. has substantiation that the above statement is truthful and not misleading.

Harry A. Shippy  
Signature  
HARRY AUGUST Shippy  
Full Name  
PR65  
Title