



JUL 21 2003

Mr. W. Paul Stewart  
President  
Doctor's Brand, LP  
2707 Hibernia Street  
Dallas, Texas 75204

Dear Mr. Stewart:

This is in response to your letter of June 20, 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 submissions state that Doctor's Brand, LP is making the following claim, among others, for the product **Liquissentials™ Joint Support Formula:**

“There is significant human and animal research showing that these ingredients support joint care. For Example: McAlindon TE, LaValley MP, Gulin JP, Felson DT. Glucosamine and Chondroitin for Treatment of Osteo-arthritis A Systematic Quality Assessment and Meta-analysis. J Amer Med Assn (JAMA) 2000;283:1459-75.”

In the preamble to the January 6, 2000 Final Rule on structure/function claims, FDA stated that placing a citation to a scientific reference that mentions a disease in the title on the immediate product label or packaging should be considered a disease claim for that product because of the unusual and unnecessary prominence of such a placement (see 65 FR 1000 at 1024). Further, we stated that for citations to scientific references that refer to a disease use in the title and that are included in other types of labeling, the agency would consider the context in which the citation is presented; one element that we stated we would look to is the prominence of the citation in the labeling. We stated that such use of a citation would not necessarily be an implied disease claim if, for example, it were not given prominence by the use of such devices as bolding, using large type size, or prominent placement (for example, the citation is simply listed in the bibliography section of the labeling among other titles). We believe that your use of the citation above (i.e., McAlindon et al.) is an implied disease claim that your product is intended for use in the treatment, prevention, mitigation, or cure of a disease (i.e., osteoarthritis). It is not one of a group of citations to articles that presents a balanced discussion of the totality of the available science about the product's ingredients; rather, it is a citation to a single review of some of the available information about studies of two of the three ingredients in your product and it is inserted conspicuously as an element of the claim itself. Therefore, the use of this citation in the manner you have used it in your promotional literature appears to be an implied disease claim under 21 CFR 101.93(g)(2)(iv)(C).

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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 a 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,



Susan J. Walker, M.D.  
Acting 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, Dallas District Office, Office of Compliance, HFR-SW140

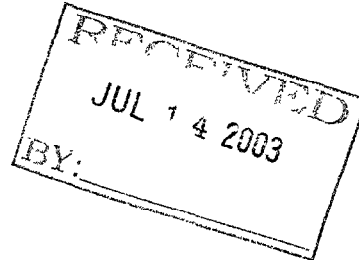
# DOCTORS' BRAND, LP

www.doctorsbrand.com

2707 Hibernia Street • Dallas, Texas • 75204  
Phone: 214.969.7348 • Fax: 214.969.9958

85021

June 20, 2003



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

To Whom It May Concern:

With this correspondence, we are notifying your office of our compliance with Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act concerning our newly introduced supplements into the marketplace.

Doctors' Brand, LP (address shown above) is the manufacturer of the following Liquissentials™ products:

Calcium Plus™  
Joint Support Formula  
Men's Multivitamin and Minerals  
Surgery and Major Injury Formula  
Women's Multivitamin and Minerals

Attached are pictures of the labels of the products, as well as a copy of the structure/function statements that are being made about them in our literature.

I hereby certify that the information contained in this notice is complete and accurate, and that we have substantiation that the statements are truthful and not misleading.

Sincerely,

A handwritten signature in black ink, appearing to read "W. Paul Stewart".

W. Paul Stewart  
President

WPS:dkw

Enclosures

RECOMMENDED BY  
LEADING PHYSICIANS

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DOCTORS' BRAND™

**LIQUID ESSENTIALS**  
JOINT SUPPORT  
FORMULA

LIQUID  
HEALTH



MAXIMUM ABSORPTION  
GUARANTEED POTENCY  
ALL NATURAL



DOCTORSBRAND.COM  
16 FL. OZ. (480 ML)

## WHY LIQUISENTIALS?

### MAXIMUM ABSORPTION

The unique patented liquid colloidal form of Liquisentials allows them to be absorbed by the body much more completely than tablets and gel caps.

### GUARANTEED POTENCY

Precise manufacturing and independent testing ensure that Liquisentials contain all of the ingredients stated on their labels, with no contaminants.

**ALL NATURAL** Liquisentials do not contain artificial colors, flavors, binders, extraction solvents, sugar, yeast, wheat, gluten, corn, dairy, sodium, starch, or alcohol.

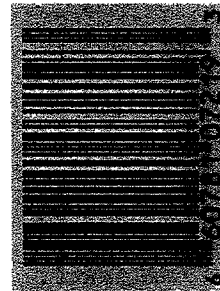
Some Doctors' Brand products may stain fabrics and surfaces. Reseal cap tightly and store upright to prevent evaporation and seepage. May be refrigerated. If necessary, rehydrate by adding water and shaking well.

For adults only. This product is not intended to treat, cure, or prevent any disease. Do not use without consulting a physician if you take prescription drugs or if a medical condition is suspected or present.

Produced by Naturally Scientific, Inc., for  
**DOCTORS' BRAND LP**, Dallas, TX 75204  
1-888-636-9657  
Patent #5785877

Supplement Facts	
Serving Size: 1 Packet (10 mL) Servings Per Container: 30	
<b>Amount Per Serving</b>	
<b>Calcium</b>	100 mg
<b>Vitamin D</b>	1000 IU
<b>Chromium</b>	200 mcg
<b>Other Ingredients</b>	Water, Glycerin, MicroActivated® Colloidal Mineral Complex, Calcium Propionate, Sodium Benzoate, Potassium Sorbate, Proprietary Flavoring Blend

Other Ingredients: BioEnhanced® Water, Glycerin, MicroActivated® Colloidal Mineral Complex, Calcium Propionate, Sodium Benzoate, Potassium Sorbate, Proprietary Flavoring Blend



### **Joint Support Formula\***

Glucosamine Sulfate, Chondroitin and MSM. Glucosamine Sulfate promotes proper joint function and repair. Chondroitin is a natural substance found in cartilage, used to support joint repair.

Methylsulfonylmethane (MSM) promotes joint repair by fortifying collagen and connective tissue. There is significant human and animal research showing that these ingredients support joint care. **For Example:**

McAlindon TE, LaValley MP, Gulin JP, Felson DT. Glucosamine and Chondroitin for Treatment of Osteo-arthritis A Systematic Quality Assessment and Meta-analysis.

J Amer Med Assn (JAMA) 2000; 283: 1459-75.

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JOINT SUPPORT  
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MAXIMUM ABSORPTION  
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16 FL. OZ. (480 ML)

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The unique patented liquid colloidal form of Liquissententials allows them to be absorbed by the body much more completely than tablets and gel caps.

Precise manufacturing and independent testing ensure that Liquissententials contain all of the ingredients stated on their labels, with no contaminants.

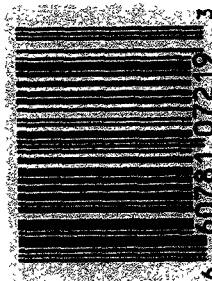
Liquissententials do not contain artificial colors, flavors, binders, extraction solvents, sugar, yeast, wheat, gluten, corn, dairy, sodium, starch, or alcohol.

Supplement Facts	
Serving Size: 1 Tablespoon (16 ml)	
Servings Per Container: 30	
Amount Per Serving	
Glucosamine Sulfate	
(as D-Glucosamine Sulfate)	500 mg*
Di-Potassium Chondroitin	400 mg*
Chondroitin Sulfate	350 mg*
MSM	

\* Daily Value not established.

Other Ingredients: BioEnhanced® Water, Glycerin, MicroActivated® Colloidal Mineral Complex, Calcium Propionate, Sodium Benzoate, Potassium Sorbate, Proprietary Flavoring Blend

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DOCTORS' BRAND LP Dallas, TX 75204  
1-888-536-9657  
Patent #5785977





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