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NOV 24 2003

Mr. Jack Hegenauer  
Director, Health Sciences & Innovation  
Shaklee Corporation  
1992 Alpine Way  
Hayward, California 94545

Dear Mr. Hegenauer:

This is in response to your letter of October 31, 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 Shaklee Corporation is making the following claims, among others, for the product **Pain Relief Complex**:

Improves restricted joints;  
Relieves discomfort in joints caused by overexertion;  
Natural pain relief for overworked joints.

These claims, including the use of the term "pain relief" in the name of the product, are disease claims because they suggest 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.

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Page 2 - Mr. Jack Hegenauer

The claims contained in your notifications do not refer to pain associated with a non-disease state. Although all consequences of "overworked" joints or "overexertion" of joints may not constitute diseases, they would not be expected to result in joint pain unless a person already suffered from an underlying disease that predisposed him or her to such pain; moreover, your claim "improves restricted joints" implicitly establishes that there are pre-existing conditions associated with the pain that your product is intended to alleviate.

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 diseases. 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.

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, San Francisco District Office, Office of Compliance, HFR-PA140

Page 3 - Mr. Jack Hegenauer

cc:

all w/copy incoming

HFA-224

HFA-305 (docket 97S-0163)

HFS-800 (file)

HFS-810 (file)

HFS-811 (Moore w/original incoming)

HFD-40 (Behrman)

HFD-310

HFD-314

HFS-607

HFV-228 (Benz)

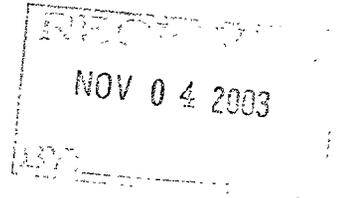
GCF-1 (Nickerson)

f/t:HFS-811:rjm:11/5/03:docname:86414.adv:disc80



**Shaklee Corporation**

October 31, 2003



Office of Special Nutritionals (HFS-810)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

**Re: Section 403(r)(6) Notification**

Dear Sir or Madam:

In accordance with the requirements of section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, Shaklee Corporation hereby notifies FDA that it has begun using the following statements:

- Pain Relief Complex (product name)
- Promotes comfortable activity
- Improves restricted joints
- Promotes flexibility
- Relieves discomfort in joints caused by overexertion
- Promotes comfortable joint movement.
- Natural pain relief for overworked joints
- Contains clinically proven *Boswellia serrata* extract
- Includes proprietary patent-pending safflower extract
- Complementary combination of natural ingredients
- Gentle on your stomach
- Laboratory tests suggest that boswellic acids may inhibit activity of the lipoxygenase enzyme.

Office of Special Nutritionals (HFS-810)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
October 31, 2003  
Page 2

- Laboratory tests suggest safflower extract selectively slows the formation of prostaglandins.

which contain the statutory statement, on the label and labeling for the following product:

**Pain Relief Complex Dietary Supplement**

I certify that the foregoing is complete and accurate, and that Shaklee Corporation has substantiation that the statements are truthful and not misleading.

Sincerely,



Jack Hegenauer  
Director, Health Sciences & Innovation  
Shaklee Corporation