



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
College Park, MD 20740

DEC 23 2003 7:07:30 AM Jbx 30 11:5

Mr. Mike Banks, Jr.  
Manager  
Banks of Eden LLC  
4692 Airport Road  
Salisbury, Maryland 21804

Dear Mr. Banks:

This is in response to your letter of November 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 Banks of Eden LLC is making the following claims, among others, for the product **Collagen Joint Therapy**:

“...supports people suffering with joint pain...other joint related ailments.”

These claims 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. Mike Banks, Jr.

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,

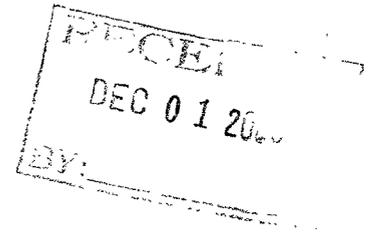


Susan J. Walker, M.D.  
Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

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, Baltimore District Office, Office of Compliance, HFR-MA240

Office of Nutritional Products Labeling  
and Dietary Supplements (HFS-810)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Point Brach Pkwy  
College Park, ND 20740



November 15, 2003

Re: Notification for Statement on Dietary Supplement Labels

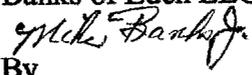
Dear Sir or Madam:

This notification is being submitted on behalf of Banks of Eden LLC, Salisbury, Maryland a distributor of dietary supplement products.

Pursuant to the requirements of Section 6 of the Dietary Supplement Health and Education Act of 1994, 21 U.S.C. § 343(r)(6), and in accordance with the authorized provisions of 21 CFR § 343 (r)(6)(A), for its dietary supplements as follows:

1. **Collagen Joint Therapy** – nutritionally supports people suffering with joint pain, stiffness or other joint related ailments. Collagen Joint Therapy should be considered an all natural nutritional food supplement. It is not a synthetic drug and contains no synthetic components. Several of the components are known structural and functional components of joints and may benefit joint related conditions.

The undersigned certifies on behalf of Banks of Eden LLC, that the information presented and contained in this correspondence is complete and accurate.

Sincerely,  
Banks of Eden LLC,  
  
By  
Mike Banks Jr.  
Manager

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