



APR 22 2004

Mr. John A. Armstrong
Vice President
PatentHEALTH LLC
5080 Aultman Avenue, N.W.
N. Canton, Ohio 44720

Dear Mr. Armstrong:

This is in response to your letter of March 11, 2004 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 PatentHEALTH LLC on is making the following claims, among others, for the product **Stolle Milk Protein Concentrate**:

“...slow the cycle of cartilage destruction, leading to joint dysfunction.”

“...prevent swelling in the joints before it starts”

“...effective in improving all measured parameters (joint pain...total WOMAC scores...”

“...protect against structural and functional damage caused by acute and chronic inflammation.”

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 statements¹ that you are making for this product suggests that it is intended to treat, prevent, or mitigate joint diseases, including arthritis. 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.

¹ The Western Ontario and McMasters Universities Osteoarthritis Index (WOMAC) survey is a questionnaire that was developed to evaluate osteoarthritis of the hip and knee. see Bellamy, N, Buchanan, WW, Goldsmith, CH, Campbell, J, Stitt, LW. 1988. Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee *J Rheumatol* 15,1833-1840.

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Page 2 - Mr. John A. Armstrong

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,

A handwritten signature in black ink, appearing to read 'S. Walker', with a long horizontal flourish extending to the right.

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, Cincinnati District Office, Office of Compliance, HFR-CE440

PatentHEALTH, LLC

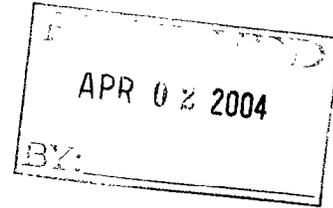
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The Office of Nutritional Products,
Labeling, and Dietary Supplements:
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy.
College Park, MD 20740



3/11/04

PatentHEALTH, LLC a distributor with its corporate offices located at 5080 Aultman Ave., North Canton, OH 44720, is **updating** its list of structure function claims for its product FLUIDjoint, whose main ingredient is Stolle Milk Protein Concentrate. The following list is comprised of claims currently being used for the product.

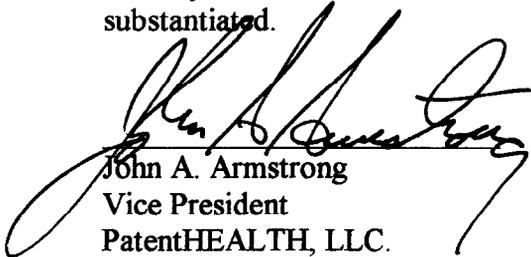
1. It's being compared to "human joint oil" for adults because of its ability to deliver powerful micronutrients to the human joints.
2. Just imagine a formula that will help your body to reduce joint discomfort, stiffness and improve flexibility to enhance daily living activities.
3. With the special micronutrients in FLUIDjoint the only "effects" experienced are more mobility, comfort and improved joint health.
4. FLUIDjoint goes directly to the cartilage and helps joints move with ease, helping to preserve cartilage and improve joint function.
5. FLUIDjoint combines micronutrients that work with our own bodies immune systems to slow the cycle of cartilage destruction, leading to joint dysfunction.
6. FLUIDjoint provides the valuable micronutrient support needed to help protect our joints.
7. FLUIDjoint helps prevent swelling in the joints before it starts.
8. A noticeable improvement in joint performance can be seen in less than 14 days of taking the daily dosage.
9. The results of one study revealed that FLUIDjoint was significantly effective in improving all measured parameters (joint pain, joint stiffness, activities of daily

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living and total WOMAC scores which measures overall joint function) beginning at the second week and continuing to the completion of the trial.

10. Clinical tests show that daily consumption of the amazing key ingredient in FLUIDjoint helps protect against structural and functional damage caused by acute and chronic inflammation.
11. It lets you move with ease.
12. Your joints can bend and flex easier so you can do all the things you love to do.
13. They (FLUIDjoint tablets) can deliver faster and increased absorption to your joints than pills.
14. Substantially greater effect over Glucosamine in improving overall joint health.

I certify that these statements are complete and accurate and their truthfulness has been substantiated.



John A. Armstrong
Vice President
PatentHEALTH, LLC.