



MAY - 5 2005

1012 5 MAY 13 P2:32

Mr. John La Puma
CEO
KneeLife LLC
P.O. Box 24039
Santa Barbara, California 93121

Dear Mr. La Puma:

This is in response to your letter of April 22, 2005 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 KneeLife LLC is making the following claims, among others, for the product **AM/PM Knee Packs**:

"[F]or pain and stiffness from osteoarthritis of the knee...[R]educe inflammation...."

"[Q]uell inflammation in your knees."

"[T]o reduce inflammation."

"[C]omplete solution to your osteoarthritis needs."

"[M]ay work to reduce your pain and stiffness...."

"[L]et your knees recover from inflammation, and reduce your pain."

"[R]educe inflammation in your bloodstream and your knees."

"Our goal is to treat osteoarthritis pain...."

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 suggest that it is intended to treat or mitigate a disease (i.e., osteoarthritis). 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.

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Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'SJW', 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-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

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

Via FedEx Next Day Air

Dr. Elizabeth Yetley
Office of Special Nutritionals (HFS-450)
Food and Drug Administration
200 C Street, S.W.
Washington, D.C.
20204

MAR 26 2011

**Re: Fulfillment of Reporting Obligation
Under 21 U.S.C.# 343(r) and 21 CFR # 101.93**

Dear Dr. Yetley:

KneeLife LLC in accordance with 21 U.S.C. # 343(r) and 21 CFR # 101.93, hereby submits an original and two copies of its notification within thirty days of first marketing its products with the statements presented below. KneeLife LLC retains scientific documentation supporting the statements.

1. Supplement Brand Name

AM/PM Knee Packs

91453

Supplement Ingredients

Supplement Facts			Supplement Facts		
Serving Size 2 packs (3 capsules/4 softgels/3 tablets) • Servings Per Container 30			Serving Size 2 packs (3 capsules/4 softgels/3 tablets) • Servings Per Container 30		
Amount Per Serving		%DV	Amount Per Serving		%DV
Vitamin A (as Vitamin A Palmitate)	5000 IU	100%	Total Omega-3 Fatty Acids	2400 mg	*
Vitamin C (as Calcium Ascorbate and Ascorbic Acid)	510 IU	1300%	Eicosapentaenoic Acid (EPA)	1440 mg	*
Vitamin D-3	600 IU	163%	Docosahexaenoic Acid (DHA)	960 mg	*
Vitamin E (as D-alpha Tocopheryl Succinate and D-alpha Tocopherol)	135 IU	450%	Glucosamine Sulfate 2KCl	1500 mg	†
Thiamine†	25 mg	1667%	Chondroitin Sulfate	1200 mg	†
Riboflavin†	20 mg	1176%	Inositol*	38 mg	*
Niacinamide†	38 mg	190%	Choline (from 38 mg Choline Bitartrate)	18 mg	*
Vitamin B-6†	35 mg	1750%	Lemon Biosavonoid Complex	13 mg	†
Folic Acid†	600 mcg	150%	Betaine HCl (from Beet Molasses)	13 mg	*
Vitamin B-12	336 mcg	9833%	Rutin (from Eucalyptus)	10 mg	*
Biotin	25 mcg	8%	PABA (para-Aminobenzoic Acid)	8 mg	*
Pantothenic Acid	38 mg	380%	Papain (from Papaya)	5 mg	*
Calcium (from Calcium Carbonate/ Citrate/Capsinate/Gluconate/Ascorbate)	1200 mg	120%	Hesperidin (from Citrus)	3 mg	*
Magnesium (from Magnesium Aspartate/ Oxide/Citrate)	360 mg	91%	Boron (as Boron Citrate)	300 mcg	*
Zinc (from Zinc Gluconate)	8 mg	63%	Proprietary Blend Betalaine HCl, Glutamic Acid HCl, Alkali, Hydrolyzed Soy Protein and Lecithin	60 mg	†
Selenium (from Selenium Selenate)	25 mcg	38%	Bromelain (standardized to mcu (milk clotting units) per mg)	6000 mcu	*
Manganese (from Manganese Amino Acid Chelate, and Manganese Sulfate)	11 mg	550%			
Potassium (from Potassium Aspartate)	0 mg	<1%			

Other Ingredients: Gelatin (capsule), natural fish oil concentrate, cellulose, vegetable stearate, mannitol/fructose complex (68 mg, approx. 1/3 calorie), glycerin, silica, water and cherry flavor.

Directions: Adults take one AM Knee Pack with morning meal, and one PM Knee Pack with evening meal daily. Use with the KneeLife® Timed Eating Plan daily. Do not substitute.

Text of Statements of Nutritional Support

The KneeLife® Program uses delicious food and safe, effective supplements taken at carefully determined times to help you reduce your knee pain†

- AM/PM Knee Packs from KneeLife® are precisely formulated dietary supplements for pain and stiffness from osteoarthritis of the knee. Water-soluble B vitamins, including extra folic acid, to reduce inflammation and homocysteine, throughout your body†
- A high dosage of purified omega-3 fatty acids from fish, to quell inflammation in your knees†
- A full day's worth of highly absorbable calcium and of the mineral manganese, necessary to rebuild cartilage†
- A high quality multivitamin to cover any gaps in your nutritional program†

They do not contain ingredients that may be harmful such as high-dose vitamin E, high fructose corn syrup, or iron, which is an oxidant, especially in postmenopausal women and in all men.†

In the morning, you receive extra Bromelain from pineapple, two-thirds your needed calcium and Vitamin D-3, half your needed omega-3 fatty acids (rich in EPA and DHA), glucosamine and chondroitin, extra B vitamins to reduce inflammation.†

AM/PM Knee Packs aim to be a complete solution to your osteoarthritis needs.

by themselves, the AM/PM Knee Packs may work to reduce your pain and stiffness,† but they are much more likely to be successful when used with the eating plan.

Our goal is to treat osteoarthritis pain using timed and dosed nutrition, supplements and behavior modification.†

If you take these supplements at the right time, you will let your knees recover from inflammation, and reduce your pain,†

Regularly taking vitamin C (500 mg/day), vitamin D (400 IU/day), folate (at least 400 mcg/day), calcium (1000-1500 mg/day) vitamin B6 (at least 6mg/day) and vitamin B12 (at least 25 mcg/day) can reduce inflammation in your bloodstream and your knees,†

In accordance with 21 USC # 343(r)(6) and 21 CFR # 101.93(c), each of the above statements of nutritional support will be followed by an asterisk that will be cross-referenced to another asterisk on the very same panel or page next to which the following statement will appear in a box in bold face type: **“These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”**

Respectfully submitted,

John La Puma
CEO, KneeLife LLC



Mailing Address:

KneeLife LLC

P.O. Box 24039

Santa Barbara CA 93121

Date of Mailing: April 22, 2005