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March 22, 2001



VIA UPS NEXT DAY AIR

Dr. Robert Moore - Chief Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C. Street, S.W. Washington, DC 20204

> Re: Fulfillment of reporting Obligation Under 21 U.S.C. § 343(r) and 21 CFR § 101.93

Dear Dr. Moore:

Pure Encapsulations, Inc., in accordance with 21 U.S.C. § 343(r) and 21 CFR § 10 1.93, hereby submits an original and two copies of its notification within 30 days of first marketing its products with the statements presented below. Pure Encapsulations retains scientific documentation supporting the statements.

1. Supplement Brand Name

Colostrum

Supplement Ingredients

Bovine Colostrum

Test of Statements of Nutritional Support

Its natural fat content has been retained to provide a colostrum supplement that promotes **optimal** protein utilization and immune function.

2. Supplement Brand Name

7-KETO DHEA

¹ The address for Pure Encapsulations. Inc. is 490 Boston Post Rd., Sandbury, MA 01776.

Supplement Ingredients

DHEA-Acetate-7-one

Text of Statements of Nutritional Support

Supports various physiological processes

Promotes basal metabolism

Helps to increase the lean/adipose ratio

Support a leaner BMI (Body Mass Index) and healthy weight control

Supported health body composition and BMI when combined with exercise

Enhancing healthy immune function and supporting memory and cognitive processes

7-KETO DHEA is a versatile, patented DHEA metabolite providing metabolic, immune and memory support without converting to the sex hormones testosterone or estrogen

3. Supplement Brand Name

Glucosamine + Chondroitin with MSM

Supplement Ingredients

Glucosamine HCL Puri tied Chondroitin Sulfate MSM (methylsulfonylmethane)

Test of Statements of Nutritional Support

Provide an enhanced spectrum of nutrients for optimal cartilage matrix composition, connective tissue strength, and joint comfort

Glucosamine promotes the synthesis of the glycosaminoglycan chondroitin sulfate

Chondroitin sulfate is responsible for building the ground substance of cartilage, molecules known as proteoglycans

Chondroitin sulfate blocks the actions of degredative enzymes

An important role of sulfur from MSM is to enhance the structure and integrity of proteoglycans

Pure Encapsulations Glucosamine and Chondroitin with MSM offers highly purified constituents for healthy cartilage formation and joint movement ease.

4. Supplement Brand Name

Echinacea Syrup

Supplement Ingredients

Echinacea syrup

50% echinacea purpurea fresh pressed juice in a base containing maltitol syrup

Text of Statements of Nutritional Support

Enhances the activity of various immune system cells and stimulates the production of molecules that also act to support healthy immune ceil response

5. Supplement Brand Name

Glucosamine + Chondroitin with Manganese

Supplement Ingredients

Glucosamine HCL Purified Chondroitin Sulfate Manganese Ascot-bate

Text of Statements of Nutritional Support

Enhanced cartilage synthesis and antioxidant support

Enhanced connective tissue support

Promotes the synthesis of glycosaminoglycans

Helps block the activity of degradative enzymes

Provide synergistic support for healthy hyaluronic acid content and synovial fluid

Supporting glycosaminoglycan and mucopotysaccharide production and encourages the antioxidant activity of superoxide dismutase

Promote joint function

Supporting optimal joint mobility and integrity

In accordance with 21 U.S.C. § 343(r)(6) and 21 CFR §101.93(c), each of the above statements 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,

Ionathan W. Emord

Claudia A. Lewis-Eng Christopher A. Brown