



7909 01 JUN 11 P2 05
MAY 31 2001

William W. Van Dyke
Chairman/CEO
Phoenix BioLogics, Inc.
2794 Loker Avenue West
Suite 104
Carlsbad, California 92008

Dear Mr. Van Dyke:

This is in response to your letter of May 16, 2001 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 submission¹ states that Phoenix BioLogics, Inc. is making the following claim, among others, for the product **OsteoCarte™**:

“Effective anti-inflammatory agent...”

“...encourage the regeneration of a patient’s own cartilage and relieve the pain associated with cartilage breakdown”

“Clinical studies are underway...to determine the effects of Hyaline™ in osteoarthritis patients.”

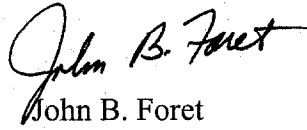
21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, cure, or mitigate disease, namely 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, 7520 Standish Place, Rockville, Maryland 20855.

¹While this is not a comprehensive review of its compliance with the mandatory labeling requirements for dietary supplements, the label submitted as part of your notification does not meet the labeling requirements for dietary supplements. The statement of identity does not meet the requirements of 21 U.S.C. 343(i) and (s)(2)(B) and 21 CFR 101.3(g) in that it does not include the term “dietary supplement.” The “supplement facts” label contains dietary ingredient declarations that are not allowed under 21 CFR 101.36(b)(2) because the dietary ingredients are present in amounts that can be declared zero (i.e., calories, fat, sodium, and carbohydrates).

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Please contact us if we may be of further assistance.

Sincerely,



John B. Foret

Director

Division of Compliance and Enforcement
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, Los Angeles District Office, Office of Compliance, HFR-PA240

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-810 (Foret)

HFS-811 (file)

HFD-40 (Behrman)

HFD-310

HFD-314 (Aronson)

HFS-607 (Bayne-Lisby)

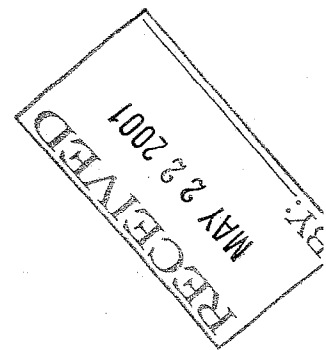
HFV-228 (Benz)

GCF-1 (Nickerson)

f/t:HFS-811:rjm:5/29/01:docname:76046.adv:disc56



76044



May 16, 2001

VitaCarte

The Original Bovine
Tracheal Cartilage

Elizabeth Yetley, Ph.D.
Office of Special Nutritionals
Center for Food Safety & Applied Nutrition
Food & Drug Administration
200 "C" Street, S.W. (HFS-455)
Washington, D.C. 20204

OsteoCarte

Liquid Bovine Tracheal Cartilage
containing Hyaline™

Dear Dr. Yetley:

Pursuant to Section 6 of the Dietary Supplement Health & Education Act of 1994, Phoenix BioLogics, Inc. wishes to notify the Food & Drug Administration that it has, within the last 30 days, commenced marketing a dietary supplement which bears a statement of nutritional support.

The dietary supplement for which the statements are made is OsteoCarte™. The statement of nutritional support reads as follows:

ArthPro

Cartilage Complex

~ A proprietary liquid cartilage blend, allowing for better absorption vs solid dosage forms.

~ Is a natural source of Chondroitin Sulfate and Glucosamine Sulfate, an essential building block of cartilage & connective tissue which promotes optimal joint, ligament & cartilage function.

~ Effective anti-inflammatory agent that also acts as an Immune Stimulant.

MediCarte

Revolutionary Topical Cream

These statements are accompanied by the required disclaimer which is prominently displayed in bold-faced type. These statements of nutritional support are based on a large body of data which, in our judgment, renders these statements substantiated, truthful and non-misleading.

Sincerely,

William W. Van Dyke
Chairman/CEO
Phoenix BioLogics, Inc.

2794 Loker Avenue West

Suite 104

Carlsbad, CA 92008

(800) 947-8482

Fax: (760) 603-0543

www.vitacarte.com

pbi@vitacarte.com

OsteoCarte™

OsteoCarte™:

- ◆ Primary component is Hyaline™ liquid bovine cartilage extract, a proprietary cartilage blend, allowing for 100% bioavailability as compared to traditional powders
- ◆ Contains naturally occurring Glucosamine Sulfate, an essential building block of cartilage and connective tissue, which helps maintain strong, flexible joints
- ◆ Immune stimulant
- ◆ Effective anti-inflammatory agent, promoting joint flexibility & mobility*
- ◆ Easily digested with no side effects
- ◆ This unique liquid suspension is non-toxic and is easily added to juice or other liquids

This unique delivery system is available exclusively from Phoenix BioLogics, Inc. in 6.8 oz. bottles.

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.



To Order or for
More Information, Call

1-800-947-8482

www.vitacarte.com

OsteoCarte™ is the only pure liquid bovine cartilage product on the market today. OsteoCarte™ contains Hyaline™, a purified bovine cartilage blend processed using proprietary technology.

OsteoCarte™ is a pure liquid extract, not a reconstituted powder. Therefore it is far more bioavailable in comparison to any Chondroitin/Glucosamine product on the market.

OsteoCarte™ penetrates into the system instantly without having to go through the destructive digestive process which allows for virtually no waste. These two components together can encourage the regeneration of a patient's own cartilage and relieve the pain associated with cartilage breakdown.

Clinical studies are underway at the University of Adelaide at Queen Elizabeth Hospital to determine the effects of Hyaline™ in osteoarthrits patients. These studies will be published in the Australian Medical Journal.

OsteoCarte™ is a trademark of
Phoenix BioLogics, Inc.
2794 Loker Avenue West, Suite 104
Carlsbad, California 92008

Hyaline™ is a patented product of
College Commodities
Maitland, Australia

OsteoCarte™ is a unique product produced with Hyaline™, a proprietary liquid bovine tracheal cartilage blend, allowing better absorption vs. solid dosage forms. Promotes optimal joint, ligament and cartilage function.

Exclusively distributed by:
Phoenix Biologics, Inc.
Carlsbad, California 92008

Hyaline™ is manufactured exclusively by
Banksia Biosciences, Ltd.
Charlestown, NSW Australia

This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Comments • Questions
1-800-947-8482
www.vitacarte.com



Hyaline™
FORMULA

OsteoCarte™

Liquid Chondroitin Sulfate

~~Approved by the TGA~~

Natural Source of Glucosamine Sulfate & Chondroitin Sulfate

6.8 Fl. Oz.

Supplement Facts

Serving Size: 5 ml (1 teaspoon)
Servings per bottle: About 40

	Amount Servings	% Daily Value
Calories	0	
Total Fat	0 mg	0.00%
Calories from Fat	0	
Sodium	7.80 mg	0.30%
Carbohydrates	0.00 mg	0.00%
Protein	0.57 g	1.14%
Hyaline™ (bovine tracheal cartilage extract)	700 mg	*

* Daily value not established

Other ingredients: water, citric acid, aniseed oil, sorbic acid, sodium erythorbate. Contains no alcohol.

Serving suggestions: Begin with 1 teaspoon 2 times daily. After symptoms subside reduce to 1 teaspoon per day.

Refrigerate after opening.

KEEP OUT OF REACH OF CHILDREN.

Batch No. Used By Date:

*While this was recently approved by the TGA, we have opted to remove this line.
(Approved as "Liquid Chondroitin Sulfate")
"OsteoCarte" is our brand name.*