



MAR 11 2005

Mr. Wallace M. Snipes
President
Corta-Flx, Inc.
P.O. Box 3807
Aiken, South Carolina 29802

Dear Mr. Snipes:

This is in response to your letter of February 2, 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 Corta-Flx, Inc. is making the claim identified below for the product **Flex-Force™**.

The product **Flex-Force™** uses the claim "Naturally helps to...ease pain from everyday activities." This claim is a disease claim because it suggests that the product is intended to treat, prevent, or mitigate diseases, namely joint disorders such as arthritis, when considered in the context of the other claims regarding the promotion of the product for joint comfort and cartilage renewal. 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 an acceptable structure/function claim could be made for pain associated with non-disease states, such as muscle pain following exercise.

97S 0163 LET 8L3

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The claim contained in your notification does not refer to pain associated with a non-disease state. Although "everyday activities" are not themselves diseases, they would not be expected to result in joint pain unless a person already suffered from an underlying disease that predisposed him or her to such 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 statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests 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 20855.

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-310
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Atlanta District Office, Office of Compliance, HFR-SE140



CORTA-FLX, INC.

P. O. BOX 3807

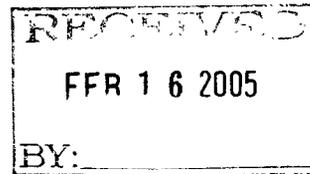
AIKEN, SC 29802

PHONE (803) 502-0433 FAX (803) 502-0094



February 2, 2005

Center for Food Safety and Applied Nutrition
Food & Drug Administration
200 C Street SE
Washington, DC 20204



ATTN: FDA Director for Dietary Supplements

Please use this letter as notification for certain types of statements on dietary supplements. I certify that the information contained in this notices in complete and accurate and our firm has substantiation that the statements are truthful and not misleading. Refer to the attached label FLEX FORCE for your review of statements.

Distributor:
Corta-Flx, Inc.
2969 Wagener Road
P. O. Box 3807
Aiken, SC 29802

Manufacturer-Packer:
Dee Cee Laboratories, Inc.
304 Dee Cee Court
White House, TN 37188

Thank you,

Wallace M. Snipes
President

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#1021

*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.

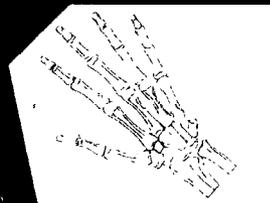


Prod. No. 193A - Rev: 011905

Flex-Force

Next to the name of the product is the text "A Unique Formulation of Nutrients Comparable to the Active Ingredients of Chondroitin and Glucosamine plus Hyaluronic Acid (HA)"

- HEAD
- NECK
- BACK
- KNEES
- HANDS
- WRISTS
- ANKLES
- ELBOWS
- SHOULDERS



60 400 mg CAPSULES

Supplement Facts

Serving Size: 1 Capsule
Servings Per Container: 60

Amount Per Serving	%Daily Value
Glucuronic Acid 64 mg	**
Glucosamine 57 mg	**
Glucosmic Acid 32 mg	**
Glycine 31 mg	**
Arginine 20 mg	**
Hyaluronic Acid 10 mg	**
Aspartic Acid 18 mg	**
Threonine 8 mg	**

**Daily Value (DV) Not Established

OTHER INGREDIENTS: Cellulose
EASY TO SWALLOW CAPSULES

*Flex-Force, a unique formulation of nutrients comparable to the active ingredients of Chondroitin and Glucosamine plus Hyaluronic Acid (HA), the major lubricating component of synovial fluid. HA complements the action of Chondroitin and Glucosamine, helping to renew cartilage and ease pain from everyday activities.

*Joint Comfort and Cartilage Renewal

DIRECTIONS for adult use as a dietary supplement: Take 1 capsule daily with a full glass of water preferably after a meal. For children, consult your healthcare professional.

WARNING: If pregnant, nursing, or taking medication, consult your physician before using this product.

STORAGE: Keep this product in a cool, dry place tightly closed.

Contains no shellfish artificial colors or preservatives

KEEP OUT OF REACH OF CHILDREN
Do not use if tamper resistant seal is broken or missing.

Dist. by: Corta-Fix, Inc. - Aiken, SC 29802
Satisfaction Guaranteed!