



Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
College Park, MD 20740-3835
USA

RECEIVED
JUN 23 2004
BY: _____

Our ref.: LDe

Tel.: +31 (0)75 629 2275

Wormerveer, June 23, 2004

Label Claims/Disclaimers

Dear Sir/Madam

This notification is being made pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, (DSHEA section 6), and in accordance with 21 CFR §101.93.

This notification concerns CLA (conjugated linoleic acid) with the brand name Clarinol™.

The owner of the product is Loders Croklaan Lipid Nutrition.

Company address:

Hogeweg 1 1521 AZ Wormerveer, the Netherlands,

US company address:

24708 W. Durkee Road, Channahon, Illinois 60410-5249

Loders Croklaan, Lipid Nutrition hereby states to have supportive evidence for the use of the following structure/function statement for Clarinol™, and supports the use of such statement on products containing Clarinol™, when used in combination with a disclaimer in accordance with 21 CFR §101.93:

Clarinol™ increases lean muscle mass

I hereby certify that the information contained in this notice is complete and accurate and that Loders Croklaan Lipid nutrition has substantiation that the statement is truthful and not misleading

Signed by:

Louis H.T. Dederen

Title: Safety & Regulatory Affairs Manager

Loders Croklaan B.V.
Lipid Nutrition
PO Box 4
1520 AA Wormerveer

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