



Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835
USA

RECEIVED
SEP 07 2004
BY: _____

Our ref.: LDe Tel.: +31 (0)75 629 2275

Wormerveer, September 1, 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 Isomerized Safflower oil with the brand name Safflorin™.

The owner of the product is Loders Croklaan Lipid Nutrition.

Company address:

Hogeweg 1, 1521AZ 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 Safflorin™, and supports the use of such statement on products containing Safflorin™, when used in combination with a disclaimer in accordance with 21 CFR §101.93:

Safflorin™ helps to stimulate the Immune System

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.
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