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December 1, 2004

VIA OVERNIGHT MAIL

Division of Standards and Labeling Regulations  
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-820)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway, Building CPK1  
College Park, Maryland 20740-3835

REC'D 01/02/2004  
AB/EOA

**RE: *Amendment to New Dietary Ingredient (NDI) Notification  
for Safflorin™ dated November 9, 2004, submitted by Loders  
Croklaan B.V.***

To Whom It May Concern:

On behalf of Loders Croklaan B.V., and in response to a telephone conversation of November 30, 2004, between Linda Pellicore and Carmen Booker of FDA, and the undersigned, this letter amends the above-referenced new dietary ingredient (NDI) notification for Safflorin™ as follows:

1. Section 2 of the notification (p. 3) is revised to include the statement, "Loders Croklaan is a bulk manufacturer of Safflorin™; it does not manufacture finished dietary supplements containing Safflorin™."
2. In section 4 of the notification (p. 4), the 2<sup>nd</sup> sentence is deleted and replaced by the following: "Loders Croklaan recommends that dietary supplement manufacturers formulate products to provide a daily intake of 2.0 g Safflorin™, which may be consumed at any time during the day in one or more separate consumption occasions."
3. In section 4 of the notification (p. 4), the 3<sup>rd</sup> sentence is deleted and replaced by the following: "The ingredient is intended for use by persons who wish to

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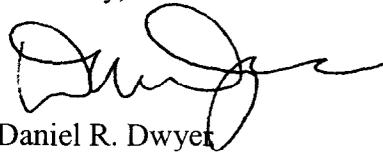
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maintain or enhance their natural resistance to stress, including everyday fatigue and environmental stress.”

Sincerely,

A handwritten signature in black ink, appearing to read "Daniel R. Dwyer", with a long horizontal flourish extending to the right.

Daniel R. Dwyer

Counsel to Loders Croklaan B.V.

cc: Linda Pellicore

Carmen Booker

Via Facsimile: 301-436-2636