

GR



ORIGINAL SUBMISSION

000001

United Grain Growers

1998 FEB 11 A 9:48

February 9, 1998

Centre for Food Safety & Applied Nutrition
United States Food and Drug Administration
200C Street S.W.
Washington DC 20204

Attention: Dr. Linda Kahl

Dear Sirs:

**RE: Solin Petition
Our File No. 97-00108 TWK**

Further to your several discussions with John Dean of United Grain Growers Limited and Don Frith of the Flax Council of Canada, we are enclosing a Notification respecting the previous Petition for Solin Oil submitted by the Flax Council. As you can see from the enclosure, the decision has been made to convert the Petition into a Notice by United, Grain Growers Limited. We are enclosing four (4) copies and would appreciate your confirming receipt and dealing with the Notification in as expeditious a manner as possible.

Yours truly,

Kirk
Corporate Counsel
& Associate Secretary

TWK/jp
Encl.

cc: John Dean
Donald H. Frith

Meeting Farmers' Business Needs

Tom Kirk Corporate Counsel & Associate Secretary

Corporate Office TD Centre 201 Portage Avenue Box 6600 Winnipeg, MB R3C 3A7

Phone (204) 944-2214 Fax (204) 944-2257

000002

GRN # 00002

Refined Solin Oil As A General Purpose
Cooking, Frying and Salad Oil and Food Ingredient

A GRAS Notification Submitted by

United Grain Growers Limited, Winnipeg, Manitoba
to the
United States Food and Drug Administration, Washington, DC

In Accordance with Proposed Section 170.36 of the
Federal Food, Drug and Cosmetic Act

January 1998

985-0103

LTR 2

1. Background

GRAS Affirmation Petition **No. 5G0416** (the "Petition") respecting Refined Solin Oil as a General Purpose Cooking, Frying and Salad Oil and Food Ingredient was submitted by the Flax Council of Canada (the "Council") in February, 1996. The Petition is currently pending before the Federal Food and Drug Administration ("FDA). The FDA has proposed amendments to the Federal Food, Drug and Cosmetic Act (the "Act") which will, if enacted, replace the existing GRAS affirmation procedure under which the Petition is pending with a notification procedure. The proposal provides for an Interim Policy under which pending petitions may be converted to a notice. The FDA would then administer such notice under the proposed new notification procedure.

The Council has consented to the Petition being converted to a notice by United Grain Growers Limited ("UGG") which is a duly constituted corporation under the laws of Canada and a member of the Council.

2. Claim

UGG (the "Notifier") claims that the use of Solin Oil (also known as Linola™ oil low linolenic acid flaxseed oil or low linolenic acid linseed oil) as a general purpose cooking, frying and salad oil, and as a food ingredient, is exempt from the premarket approval requirements of the Act because it has been determined that such use is generally recognized as safe (GRAS). The basis for the GRAS determination is the substantial equivalency of Solin Oil to other vegetable oils in common use, sunflower oil and safflower oil, in particular.

3. Name and Address of Notifier

United Grain Growers Limited
TD Centre
201 Portage Avenue
Box 6600
Winnipeg, Manitoba Canada
R3C 3A7

4. GRAS Petition Number

5G0416

5. Name

5.1 Generic Name

Solin Oil

5.2 Common or usual name

Linola™ oil, low linolenic acid flaxseed oil or low linolenic acid linseed oil.

6. Condition of Use

Solin Oil would be used as a general purpose cooking, frying, and salad oil, and as an ingredient in margarines, shortenings, and other food products. It would substitute for other vegetable oils, and mixtures of oils in common use. The extent of its use would be determined by its price, functionality and availability.

7. Basis for the GRAS Determination

The claim for exemption of Solin Oil from pre-market approval is based on scientific procedures, as presented in the Petition which also describes the development of Solin Oil from flaxseed (linseed) and the method of manufacture, characteristics, properties, and food-grade specifications of Solin Oil.

8. Records

The complete record that supports the GRAS determination has been submitted previously to the FDA by the Council in the Petition, all of which is incorporated herein by reference.

9. Request for Response Letter

The Notifier respectfully requests that the FDA provide a response letter confirming that:

SUBMISSION END

000007