



Memorandum

AUG 30 2000

Date

From

(Acting) Division Director, Division of Standards and Labeling Regulations, Office of  
Nutritional Products, Labeling and Dietary Supplement, HFS-820

Subject

75-Day Premarket Notification for New Dietary Ingredients

To

Dockets Management Branch, HFA-305

New Dietary Ingredient:

tree oil phytosterols

Firm:

Novartis Consumer Health, Inc.

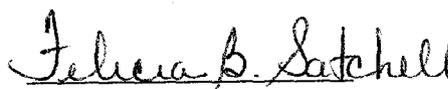
Date Received by FDA:

June 19, 2000

90-Day Date:

September 16, 2000

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and  
Cosmetic Act, the attached 75-day premarket notification for the aforementioned new  
dietary ingredient should be placed on public display in Docket No. 95S-0316 after  
September 16, 2000.

  
Felicia B. Satchell

955-0316

RPT 77



AUG 30 2000

Scott Bass, Esq.  
Sidley & Austin  
1722 Eye Street, NW  
Washington, DC 20006

Dear Mr. Bass:

This is to notify you that the submission you filed on behalf of your client Novartis Consumer Health, Inc. pursuant to section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act), dated June 16, 2000, concerning the marketing of a substance (i.e., tall oil phytosterols) that Novartis Consumer Health, Inc. asserts is a new dietary ingredient was received by the Food and Drug Administration on June 19, 2000. This submission will be kept confidential for 90 days from the date of receipt and, after September 16, 2000, will be placed on public display at Dockets Management Branch (Docket No. 95S-0316). Commercial and confidential information in the notification will not be made available to the public.

Please contact us if you have any questions concerning this matter.

Sincerely yours,

Felicia B. Satchell  
(Acting) Division Director  
Division of Standards  
and Labeling Regulations  
Office of Nutritional Products, Labeling  
and Dietary Supplements

# SIDLEY & AUSTIN

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WRITER'S DIRECT NUMBER  
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WRITER'S E-MAIL ADDRESS  
sbass@sidley.com

June 16, 2000

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street, SW  
Washington, DC 20204

*Received*  
*6/19/00*  
*RFP*

Re: New Dietary Ingredient Notification

Dear Sir or Madam:

On behalf of Novartis Consumer Health, Inc. ["Novartis"], we submit the attached information, pursuant to section 413(a) of the Federal Food, Drug and Cosmetic Act, in support of Novartis' marketing of the new dietary ingredient tall oil phytosterols (under the trade name Reducol™). Novartis intends to market this ingredient for dietary supplement use.

Novartis submitted to the Agency on December 13, 1999, a summary of information pertaining to the use of tall oil phytosterols as a food ingredient, in the format outlined in proposed regulation 21 CFR 170.36 [62 FR 18938, Substances Generally Recognized as Safe (GRAS)]. This submission informed the Agency of Novartis' conclusion, and that of its Expert GRAS Panel, that tall oil phytosterols are generally recognized as safe (GRAS) for use in vegetable oil spreads.

On April 24, 2000, the Food and Drug Administration informed Novartis in a letter that, based upon their evaluation of the submission and other available data, the Agency had no questions regarding Novartis' conclusion that tall oil phytosterols are GRAS under the intended conditions of use. The Agency's response, the evaluation and conclusion of an Expert GRAS Panel, and the

RECEIVED  
6/19/00

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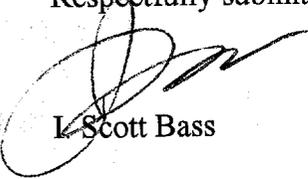
Office of Special Nutritionals (HFS-450)

June 15, 2000

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scientific information cited in the submission, serve as the scientific basis for Novartis' conclusion that the tall oil phytosterols as a dietary ingredient can "...reasonably be expected to be safe."

Respectfully submitted,



L. Scott Bass

cc: Judith Weinstein, Esq.  
Associate General Counsel  
Novartis Consumer Health, Inc.

**New Dietary Ingredient Notification**  
**for Tall Oil Phytosterols**  
**(Trade Name Reducol™)**

**Novartis Consumer Health, Inc.**

**June 16, 2000**

**SECTION 1**

**The name and complete address of the manufacturer or distributor of the dietary supplement that contains the dietary ingredient, or the dietary ingredient.**

The distributor of the dietary ingredient will be:

Novartis Consumer Health, Inc.  
560 Morris Avenue  
Summit, New Jersey 07901-1312

Attention: Judith Weinstein, Esq.  
Associate General Counsel

## SECTION 2

### **The name of the dietary ingredient.**

The dietary ingredient is tall oil phytosterols (trade name Reducol™).

Tall oil phytosterols are derived from the unsaponifiable matter of oil derived from trees. Tree oil is commonly referred to as tall oil. The dietary ingredient contains significant levels of sitosterol, campesterol, and the naturally occurring saturated (stanol) compounds, sitostanol and campestanol. Stigmasterol and other sterols are also found in minor quantities. The phytosterols are in a free non-esterified form.

### SECTION 3

**Description of the dietary supplement or dietary supplements that contain the dietary ingredient including (i) the level of the dietary ingredient in the dietary supplement, and (ii) the conditions of use recommended or suggested in the labeling of the dietary supplement, or if no conditions of use are recommended or suggested in the labeling of the dietary supplement, the ordinary conditions of use of the supplement.**

The dietary ingredient, tall oil phytosterols, will be marketed for use in products meeting the definition of "dietary supplement" in section 201(ff) of the Federal Food, Drug and Cosmetic Act. The tall oil phytosterols will be clearly labeled and promoted as dietary supplements. Each serving of the dietary supplement will contain 0.6 g of tall oil phytosterols. Consumption of up to 3 servings per day will be suggested or recommended in the label directions, resulting in maximum daily consumption of up to 1.8 g of tall oil phytosterols. This level of intake is within the level of dietary exposure considered safe for use in food.

#### SECTION 4

**The history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe, including any citation to published articles or other evidence that is the basis on which the distributor or manufacturer has concluded that the dietary supplement will reasonably be expected to be safe.**

A summary of information pertaining to the use of tall oil phytosterols as an ingredient in food was submitted by Novartis Consumer Health, Inc. on December 13, 1999 as part of a GRAS notification to the Agency. The information served as the foundation for Novartis Consumer Health's conclusion that tall oil phytosterols are safe (GRAS) for use in vegetable oil spread. Of primary importance was the evaluation and conclusion of the Expert GRAS Panel.

The April 24, 2000 letter from the Food and Drug Administration stated that, following their evaluation of the materials, FDA had no further questions regarding Novartis Consumer Health's conclusion that, at a level of 0.5 g of tall oil phytosterols per serving (referenced to 70 kg bw) of food for up to 3 servings per day, tall oil phytosterols are GRAS for use in food.

The opinion that the dietary ingredient tall oil phytosterols meets the statutory requirement under section 413(a)(2) that it will be "...reasonably expected to be safe..." is based upon the materials and information submitted in support of the GRAS notification, updated to include information available since the December 13, 1999 notification, the Expert GRAS Panel Report, and the April 24, 2000 letter from FDA.

Information provided to support Novartis Consumer Health's conclusion of safety is as follows:

- Attachment 1 – Statement of the GRAS Expert Panel.
- Attachment 2 – The updated list of scientific articles which form the basis for the opinion of safety. References that have become available since the December 13, 1999 notification, or have been updated with respect to their current publication status, are identified in **bold**.
- Attachment 3 – April 24, 2000 letter from the Food and Drug Administration to Novartis.
- A copy of the listed references is included with the original document.

  
Judith Weinstein, Esq.