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**VIA FEDERAL EXPRESS**

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Room 1061
HFA-305
Rockville, MD 20852

COPY

**Re: Health Claims; Plant Sterol/Stanol Esters and Coronary Heart Disease; Interim Final Rule. (Docket nos. 00P-1275 and 00P-1276.)**

Dear Sir or Madam:

On November 21, 2000 and May 11, 2001, Arent Fox, on behalf of its client, Raisio Benecol Ltd. ("Raisio"), filed comments on FDA's above-referenced Interim Final Rule. A large number of published clinical studies were cited by both FDA in its proposed rule, and by Raisio in its comments.

Raisio has received information that orange juice and other low fat and fat-free beverages may soon be launched on the US market. In view of that possibility, we would like to draw your attention to the enclosed paper that has just been published in the current issue of the Journal of Lipid Research. The paper is titled "Phytosterols in low- and nonfat beverages as part of a controlled diet fail to lower plasma lipid levels," and was written by Peter Jones and others at McGill University in Canada. In its Interim Final Rule, FDA relied heavily on another of Dr. Jones' studies, the 2000 paper "Modulation of plasma lipid levels and cholesterol kinetics by phytosterol versus phytostanol esters." That paper, which was funded by Lipton Inc. Canada, failed to show the efficacy of low-dose stanol esters in reducing plasma cholesterol levels, and FDA accepted those findings, declining to accept low doses of plant stanol esters.

In the current study, a non-esterified phytosterol mixture consisting of 60% sitosterol, along with smaller quantities of sitostanol and campesterol, dispersed in non-fat or low-fat beverages consumed three times daily with controlled, relatively high-fat meals, failed to reduce plasma total or LDL-cholesterol. The total daily intake of phytosterols was 1.8 grams, an intake that other researchers have shown to be efficacious when administered in solid food form. In the Discussion section of the paper, Dr. Jones suggests that this efficacy failure may have been due to a lack of esterification of the phytosterols. Raisio has always maintained that its phytostanol esters are more effective in blocking cholesterol absorption from the gastrointestinal tract when used in

00P-1276 SUP 2

various food forms as compared to the free phytosterols at, and the results of this new study would appear to lend support to that position.

Raisio recognizes that the administrative record for filing comments on the Interim Health Claim for Stanol/Sterol esters has closed. However, in the interest of sound science Raisio believes it important to acquaint the agency with the results in this paper, especially when they are inconsistent with other reports relied on by FDA.

Very truly yours,

Marsha C. Wertzberger
Counsel to Raisio Benecol Ltd.

cc: Christine Taylor, Ph.D.