



Publisher of **Nutrition Action Healthletter**

November 9, 2001

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Docket Nos. OOP-1275 and OOP-1276

The Center for Science in the Public Interest (CSPI)¹ is pleased to submit the following comments on the Food and Drug Administration's (FDA) interim final rule authorizing health claims for plant stanol/sterol esters and coronary heart disease. In particular, we commend the Agency for reopening the comment period, in part, as a response to decisions by other nations to require labeling which states that it may not be appropriate for specified subgroups of the population to consume products containing plant stanol/sterol esters.

CSPI believes that the FDA should harmonize its regulations with those of the European Union (EU) and Australia and New Zealand by requiring products making such claims to bear an advisory that the product may not be appropriate nutritionally for pregnant and lactating women and children under the age of five. The basis of the EU and Australia-New Zealand's concern is that phytosterols may cause a reduction in blood beta-carotene levels and, therefore, products containing phytosterols may not be appropriate for pregnant and lactating women and young children whose vitamin A status is not optimal. Until long-term studies demonstrate that these products can be safely used by pregnant and lactating women and children under the age of five,

~~OOP-1275~~

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¹ CSPI is a non-profit consumer organization supported by 850,000 members that has worked since 1971 to improve national health policies.

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CSPI

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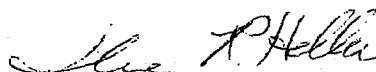
Michael F. Jacobson, Ph.D.
Executive Director

we believe that the labels on these products should advise consumers that phytosterols are not appropriate for these specific subgroups.

CSPI believes that the failure to include such an advisory causes a product to be misbranded within the meaning of sections 403(a) and 201(n) of the Federal Food, Drug and Cosmetic Act. Most foods, including conventional margarines, can be eaten by all members of a household over the age of one, unless someone suffers from food allergies or intolerances. But, parents who use plant stanol/sterol ester containing spreads as part of a cholesterol-lowering program may be unaware that the product may not be appropriate for children under the age of five. Similarly, women of child-bearing age may not be aware that consumption of cholesterol-lowering products is not appropriate if they are pregnant or nursing. The failure to include information alerting consumers that the product is not appropriate for these subgroups thus constitutes an omission of facts material with respect to consequences that may result from the use of a product.

Therefore, we urge the agency to adopt a rule requiring an appropriate advisory statement.

Respectfully submitted,



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CSPI CENTER
FOR SCIENCE
IN THE
PUBLIC INTEREST
Publisher of *Nutrition Action Healthletter*

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Subject: Comments on Docket Nos. 00P-1275 and 00P-1276

Comments: