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May 1, 2000

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

RE: Food Labeling: Dietary Supplement Health Claims; Public Meeting  
Concerning Implementation of Pearson Court Decision and Whether  
Claims of Effects on Existing Diseases May be Made as Health Claims  
Docket No. 00N-0598 65 Fed Reg 14219 (March 16, 2000)

Dear Sir/Madam,

The agricultural products business of Pharmacia Corporation, formerly known as Monsanto Company, is committed to improving health by increasing the availability and nutritional value of food products, including dietary supplements. We are research-based and committed to demonstrating the value of our products via sound scientific evidence. We submit these comments in response to the above-named request for public comment.

#### Summary

1. We believe FDA should continue to evaluate proposed health claims on the basis of "significant scientific agreement" (SSA) as required under the Nutritional Labeling and Education Act. Qualifiers and disclaimers should be used to make proposed health claims more accurate and understandable to consumers, provided that the claims are potentially, as opposed to inherently, misleading.
2. As a business committed to developing sound scientific evidence for the health benefits of our products, we continue to believe that the health claims approval process should be expedited by an industry-sponsored third party review process.
3. Although the Pearson decision applied to health claims on dietary supplements, we believe it is appropriate for FDA equally to apply to

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traditional foods any changes in policy and regulations it makes when implementing Pearson for dietary supplements.

4. We believe that the range of acceptable health claims should include claims that accurately describe the relationship between a food or dietary supplement and disease and should not be limited to disease risk reduction.

FDA should continue to apply the SSA standard and use qualifiers and disclaimers to make health claims reflect the supporting data more accurately.

The Court of Appeals concluded in the Pearson case<sup>4</sup> that proposed health claims that were found by FDA not to meet the SSA standard could, nevertheless, be made if they were appropriately qualified such that they met the standard or at a minimum were not false and misleading. At the same time, the Court asked FDA to define SSA or at least explain on a case-by-case basis what the standard means. Had the Court intended for the SSA standard to be abandoned, the SSA provisions of NLEA would become moot. Our reading of the decision does not suggest this intent.

In implementing the Pearson decision, we believe FDA should continue to apply the SSA standard in its evaluation of proposed health claims and should explain the bases on which a claim is allowed or not. This will help other submitters understand what they must do to satisfy the standard. Qualifiers and disclaimers should be used to allow claims to reflect more accurately the nature of the relationship between the product and health. For example, a health claim describing the effect of a dietary component on blood cholesterol could be made more accurate by the addition of qualifying information, eg, "Results from clinical studies on people with moderately elevated blood cholesterol show that product x helps reduce blood cholesterol."

We urge FDA to bear in mind the confusion that may be created among consumers by the use of disclaimers and qualifiers that make the claim obtuse to the average consumer. For example, we do not believe it is reasonable to expect consumers to weigh the relative merits of data from case-control studies vs. intervention studies that might be referenced in qualified health claims.

We also encourage FDA to bear in mind the Court of Appeals' acknowledgment that there are situations where disclaimers will not remedy the misleading effect of a health claim, ie, where supporting evidence is outweighed by evidence against the claim or where there is evidence a disclaimer would be insufficient to protect against deception. We urge FDA

to use the authority provided by the Court not to approve such claims to help maintain the credibility of well-substantiated health claims.

An independent, third party review process for health claims is needed.

In its document, "Guidance for Industry. Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements," issued 12/22/99, FDA stated,

"In determining whether there is significant scientific agreement, FDA takes into account the viewpoints of qualified experts outside the agency, if evaluations by such experts have been conducted and are publicly available. For example, FDA will take into account:

- documentation of the opinion of an 'expert panel' that is specifically convened for this purpose by a credible, independent body..."

We enthusiastically support this independent third party option. The existence of such an entity would accomplish three goals:

- the assurance that consumers are provided information about products that is appropriately substantiated;
- manufacturers could be assured of a timely review process and would have the incentive to invest in research to develop useful products;
- FDA would be relieved of the burden of reviews of numerous health claim petitions, while being assured that claims were evaluated independently and objectively, and instead could devote its resources to other high priorities.

This appears to be a "win-win-win" for all sides. We urge FDA to work with the key drivers of the creation of such an entity, the Research-based Dietary Ingredient Association and the Life Sciences Research Office, and support their efforts to establish such a review process.

FDA's implementation of Pearson should apply to conventional foods

We believe there is no basis, legal or otherwise, for applying different scientific standards for health claims on dietary supplements vs. conventional foods. Such a distinction would place food manufacturers at a competitive disadvantage to dietary supplement manufacturers and could create consumer confusion about the validity of health claims in general. If dietary

supplements are to play a useful role in consumers' management of their health, their claims should be no less substantiated than those made on conventional foods.

Health claims should include claims about effects on disease other than risk reduction

Our reading of the NLEA provides no indication that Congress intended health claims to be limited to disease risk reduction claims. We note that vitamins and minerals at RDI levels of intake have been known for decades to prevent, treat, and cure diseases and yet are not viewed as drugs, and claims about their effects are exempt from regulation as drug claims. It appears that the view that these substances are nutrients as opposed to drugs is based on tradition rather than a scientific principle.

We believe that as other disease preventing, treating, and curing effects of components in foods are recognized, these benefits should be truthfully reflected in labeling, and not shrouded in code words such as "may reduce the risk." In light of FDA's recent final rule on structure/function claims, which determined that claims about effects of dietary substances on biomarkers of disease are implied health claims, we believe it is essential for health claims to include claims about disease prevention, treatment and mitigation.

We appreciate this opportunity to provide our views and hope these comments are useful.

Respectfully submitted,

A handwritten signature in black ink that reads "Maureen Mackey". The signature is written in a cursive style with a horizontal line under the name.

Maureen Mackey, Ph.D  
Group Lead, Nutrition Regulatory Affairs

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# SEARLE

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