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Congress of the United States
House of Representatives

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February 22, 2000

BY FACSIMILE

The Honorable Jane E. Henney
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: FDA Docket No. 99D-5424

Dear Dr. Henney:

I am writing to comment on and ask questions about the Food and Drug Administration's (FDA) December 22, 1999 draft "Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements."

By enacting the Nutrition Labeling and Education Act of 1990 (NLEA), Dietary Supplement Health and Education Act of 1994 (DSHEA), and the Food and Drug Modernization Act of 1997 (FDAMA), Congress provided that FDA encourage increased consumer access to new nutritional information as long as such information is truthful and adequately substantiated. In 1999, the United States Court of Appeals for the District of Columbia Circuit found that, under the First Amendment, FDA may not continue to apply the "significant scientific agreement" standard to ban health claims based on emerging scientific evidence where the claim may be stated using qualifying language and/or disclaimers to accurately reflect its supporting scientific substantiation (*Pearson v. Shalala*, 164 F.3d 650 D.C. Cir. 1999).

However, in section II. E. of the draft guidance, FDA apparently plans to apply the "significant scientific agreement" standard to the overall substance-disease relationship, rather than to a proposed, specific health claim. The level of scientific agreement for a specific claim, which may include qualified language and disclaimers, is likely to be less than that required to prove the overall substance-disease relationship. For example, the scientific evidence needed to substantiate a specific health claim (e.g., "emerging research indicates that consumption of three

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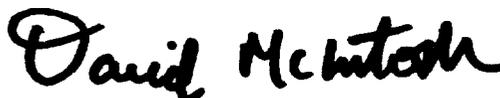
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servings a day of a particular food may reduce the risk of contracting a certain disease for people over fifty”) is likely to be less than that needed to conclusively establish the entire substance-disease relationship. The approach employed in the draft guidance ignores the reality that scientific progress establishing diet-disease relationships is incremental. Thus, applying the “significant scientific agreement” standard to the proposed claim, as opposed to the entire substance-disease relationship, properly implements the Congressional goal of providing increased nutritional information to the public.

Therefore, pursuant to the Constitution and Rules X and XI of the United States House of Representatives, I request that you answer the following two questions. First, please explain how the guidance’s application of the “significant scientific agreement” standard reconciles with the First Amendment, NLEA, DSHEA, FDAMA, and the *Pearson* case. Second, will the guidance’s application of the “significant scientific agreement” standard allow the communication to consumers of properly qualified health claims (or those with disclaimers) explaining new and emerging scientific findings?

Please deliver your response to the Subcommittee majority staff in B-377 Rayburn House Office Building and the minority staff in B-350A Rayburn House Office Building not later than noon on Friday, March 10, 2000. If you have any questions about this request, please call Subcommittee Counsel Bill Waller on 226-2067. Thank you for your attention to this request.

Sincerely,



David M. McIntosh

Chairman

Subcommittee on National Economic Growth,
Natural Resources, and Regulatory Affairs

cc: The Honorable Dan Burton
The Honorable Dennis Kucinich
The Honorable Helen Chenoweth-Hage

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Dan Burton
M.C.

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



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