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February 22, 2000

Dr. Jane Henney, Commissioner
Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane, Rm. 1061
Rockville Maryland 20852

Docket No. 99D-5424

Dear Commissioner Henney:

We are writing to comment on FDA's "Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements" published on December 22, 1999.

Citizens believes that FDA's Guidance Document is a positive step toward explaining the agency's approach to evaluating the validity and amount of scientific evidence for health claims. However, the Guidance Document fails to meet requirement by the US Court of Appeals to define significant scientific agreement. We believe that FDA should define significant scientific agreement, as ordered by the Court.

Does FDA define significant scientific agreement to be the same as scientific consensus in the manner of a National Institutes of Health consensus conference? If it does not, FDA should say it does not. Does FDA define significant scientific agreement to mean substantial evidence as used in the 1963 new drug amendments? (The legislative history makes clear that substantial evidence of efficacy is more than a scintilla of evidence since this Act was intended to be an anti-fraud action.) If it does not, FDA should say so. If FDA does not place significant scientific agreement at one or the other of these ends of the scientific evidence continuum, it should in order to comply with the Court's directions. FDA should state where on the continuum the agency places the significant scientific agreement standard.

FDA cited The Keystone National Policy Dialogue on Food, Nutrition, and Health in the Background Information of the Guidance Document, stating that "the dialogue and resulting report affirmed the principles and approach FDA had been using to authorize health claims." The Keystone dialogue concluded its work prior to the findings of the Court in *Pearson, et. al. v. Shalala* and thus before the directions to FDA by the Court to define significant scientific agreement.

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As James S. Turner, *Citizens'* Board chair and member of the Keystone Dialogue Group points out in the attached memo (Attachment One), the Dialogue Group never addressed the issue of defining significant scientific agreement in the manner directed by the US Appeals Court in Pearson. The Pearson case was pending at the time the dialogue was held and the dialogue did not address the question of defining significant scientific agreement in the terms used by the Court in defining significant scientific agreement.

The Keystone Dialogue had extensive discussions about FDA's requirement that a health claim be supported by proof of a mechanism of action, a theoretical model, and clinical studies before a claim could be made. The dialogue's section on significant scientific agreement did not address this issue. We feel strongly that FDA must not, and legally cannot, deprive consumers of truthful, non-misleading information about the relationship between nutrients and health. The extent that FDA has been and appears to be continuing to use significant scientific agreement to deny such information is against the Court's order.

FDA must find ways to ensure that the public receives, through commercial channels, all dietary supplement information that is not inherently misleading. This requires FDA to abandon 50 years of regulatory bias against supplements. FDA must embrace dietary supplements and their users as allies in the campaign for better health.

Citizens would like to reiterate positions on FDA's significant scientific agreement standard from our document, "An Opportunity to Lead: Overall Strategy for FDA Regulation of Dietary Supplements Through Sound Information Rules," that we submitted for FDA Docket No. 99N-1174. FDA should:

- Establish a definition of significant scientific agreement designed to inform consumers, not to resolve scientific controversy. (Opposing sides of a scientific controversy could both be supported by significant scientific agreement.) The definition must recognize substantial, not conclusive, evidence (more than a scintilla though not a preponderance) as the standard to support claims.
- Recognize, and reinstate the proposal that "preliminary" evidence -- evidence supported by significant scientific agreement that an effect might (though conclusive evidence has not been established) be connected to a supplement -- be permitted on labels and in labeling.

Citizens strongly urges FDA to encourage the broadest possible availability of health benefit information on the labels of dietary supplements as the primary way to ensure that consumers get the widest choice of the safest nutrients available in the market.

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With interest in dietary supplements crossing age, racial, economic, and educational divisions, consumers are demanding more opportunities to inform themselves about the health benefits of supplements. Expanding the use of health claims is an important aspect of fulfilling the Congressional and public intent in passage of the Dietary Supplement Health and Education Act of 1994 (DSHEA). Consumers want the opportunity to take control of their own health. The public has shown time again with their dollars and their voices that they want to use dietary supplements and that they are willing to fight for the right to make informed health choices.

FDA's continued insistence on banning health claims that are generally accepted by the scientific community until they are conclusively proven to a standard virtually indistinguishable from that required of a new drug has had unacceptable consequences on consumer health. Such action led to the deplorable situation where FDA's failure to approve widely accepted scientific claims for folic acid's prevention of birth defects may have led to as many as 2,500 children suffering damage that could have been prevented through consumption of folic acid.

In the Background Information section of FDA's Guidance Document, the agency contends that, "The Commission on Dietary Supplement Labels examined the health claim authorization process for dietary supplements and also generally expressed agreement with FDA's approach in its report." However, the Commission, mandated by DSHEA, actually challenged the FDA's narrow interpretation of "significant scientific agreement." The Commission statement included:

- "the standard of scientific agreement should not be so strictly interpreted as to require unanimous or near-unanimous support"
- "FDA should ensure that broad input is obtained to ascertain the degree of scientific agreement that exists for a particular health claim" and "the use of appropriate panels of qualified scientists from outside the agency is encouraged"
- "that consumer understanding of nutritional support and health claims are important aspects of the information that require additional and continued assessment"

The FDA Reform bill passed in November 1997 expanded the assessment of what health claims might be allowed, and allows health claims to be made on dietary supplement labels if a scientific body of the federal government, like NIH or CDC, has published an "authoritative statement" on the nutrient-disease relationship on which the claim is based. However, this provision does not make real advances in allowing health claims, because FDA continues to have the final word on approving the applications for health claims on

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labels. Additionally, FDA still must define its "significant scientific agreement" standard for the health claim applications that have not been addressed by a "scientific body" of the federal government.

Citizens urges that the agency move closer to addressing the definition of significant scientific agreement as ordered by the US Court of Appeals in its ruling in *Pearson v. Shalala*. *Citizens* also believes that the use of disclaimers, such as those considered by the Appeals Court in the *Pearson v. Shalala* case, should be considered in determining what requirements should apply to health claims based on "authoritative statements."

FDA should permit statements on labels that are supported by significant scientific agreement, including but not limited to "authoritative statements," even if they are preliminary suggestions about possible health benefits, as long as their nature is indicated.

Citizens urges the overarching policy that the full, robust flow of information is the best way to create both safety and choice for the consumer. In every instance in which FDA looks at a health statement on a label it should expand the opportunity for information to be made available to the consumer.

Sincerely,



Susan Haeger
President/CEO

Attachment One

15 Feb 2000
Memorandum

From: James S. Turner, Esq. Board Chair *Citizens for Health*
To: Susan Haeger, President, and CEO *Citizens for Health*

1. I served as a member of both the Keystone Dialogue on Food Nutrition and Health and on the Dialogue steering committee. The Dialogue was my idea. I contacted Food Industry members of the Food Safety Council (which I also played a key role in organizing) active in the late 70's and early 80's. (Most notably I worked with Al Clausi, former president of Institute of Food Technologists, the Food Safety Council and Vice President for Research of General Foods to establish the Dialogue.) I suggested that we form a collaborative activity to review the difficulties that consumers and industry were having using the Nutrition Labeling and Education Act in significant part because of the FDA's peculiar reading of the "significant scientific agreement" standard. That suggestion became the Dialogue. Along with food industry representatives, I interviewed the Keystone group, helped choose Keystone as the home for the activity and participated in the meetings that persuaded FDA to join the process.

2. The Keystone Dialogue Group finished its work prior to the Federal Court finding in *Pearson v Shalala* that directed the FDA to define "significant scientific agreement." However one reads the language of the Dialogue, it cannot be sighted as an answer to the Court directive to define the meaning of the words in question since the Dialogue completed its work prior to the Court ruling. Either the Dialogue group agreed with FDA and so was, in light of the Court finding, as incorrect as FDA. Or the Dialogue did not support FDA either directly or indirectly. In fact, the Dialogue did not focus on the definition of "significant scientific agreement" but rather on how the FDA was using the concept in its regulatory function. To the extent that the Dialogue view of "significant scientific agreement" differed from the directions of the Court, the Court ruling controls and FDA must follow it.

3. I participated in meetings of the "significant scientific agreement" sub-group of the Dialogue and heard the FDA suggest that "significant scientific agreement" consisted of a series of steps that closely paralleled the requirements for proof of efficacy of a drug and proof of safety of a food additive. In order to make a health claim related to a nutrient, FDA seemed to say, one needed a hypothesis of why the claim and the nutrient were connected, a mechanism of action, and clinical data to demonstrate both the hypothesis and the mechanism. Nowhere in the legislation, the legislative history or the Keystone Dialogue is there an endorsement of this approach and, during the Dialogue, there was great distress at the FDA approach. Indeed the FDA's own original regulation indicated that the legislation allowed FDA to recognize that "significant scientific agreement" could support the possibility of a connection between a nutrient and a health claim based on *preliminary* information as long as the basis of the claim was clear. I do not think the Dialogue supports FDA's restrictive definition of "significant scientific agreement."



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FACSIMILE COVER SHEET

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 From: Citizens For Health
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hard copy in the mail