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

RE: Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements
Docket No. 03N-0069
67 Fed. Reg. 78002 (Dec. 20, 2002)

AARP appreciates this opportunity to present its views on the guidance document, issued by the Food and Drug Administration (FDA) in December 2002 that allows labels of conventional foods and dietary supplements to include "qualified" health claims. Before addressing some of the specific questions posed by the FDA, we would like to address a number of threshold issues.

General Issues

The law allows only those health claims on food labels that are supported by "significant scientific agreement."

First, FDA's decision to allow health claims on the labels of conventional foods should meet the statutorily mandated standard. The Federal Food Drug and Cosmetic Act (FFDCA), as amended by the Nutrition Labeling and Education Act (NLEA) of 1990, authorizes FDA to approve health claims for conventional foods "*only* if the Secretary determines, based on the totality of the publicly available scientific evidence . . . that there is significant scientific agreement . . . " that the claim is supported by such evidence.[1]

In a 1999 decision, *Pearson v. Shalala*,[2] the U.S. Court of Appeals for the D.C. Circuit ruled on the constitutionality of the FDA's regulations governing health claims for dietary supplements. The court held that, on the administrative record compiled in the rulemaking, the first amendment does not permit FDA to reject health claims on supplement labels that the agency determines to be potentially misleading unless the agency also reasonably determines that a disclaimer would not eliminate the potential deception.

Until it issued the guidance document at issue here, FDA has consistently, repeatedly, and appropriately limited the *Pearson* decision to dietary supplements, the products that were at issue in this case. The FFDCA treats conventional foods and supplements differently in a number of instances, including where health claims are at issue: the statute requires that health claims for conventional foods be supported by "significant scientific agreement," but leaves to FDA the determination of the appropriate standard for supplement claims.

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[1] 21 U.S.C. § 343(r)(3)(B)(i)(emphasis added).
[2] 164 F.3d 650 (D.C. Cir.1999).

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The guidance document reverses FDA policy, without providing any reasonable rationale or justification for the change. Without such a basis, FDA's reversal constitutes the type of "arbitrary and capricious" action that is generally prohibited under the Administrative Procedure Act.[3]

The law allows only those health claims that are authorized through agency regulations.

Second, the decision should follow the statutorily prescribed health-claim procedure for approving qualified health claims. The FFDCA generally allows only those health claims that are established by regulations developed through a notice-and-comment procedure. Under such a procedure, FDA issues a proposed regulation that would allow for a specific claim; interested parties have an opportunity to submit comments on the proposal; the agency reviews the comments and, where appropriate, revises and then finalizes the regulation.[4] The exemptions to this procedure that are recognized by the law – one for "authoritative statements" and the second, allowing for interim regulations – are not applicable here. FDA's failure to provide an opportunity for public comment, undermines the statutory framework and the agency's ability to enact optimal regulations.

FDA unduly relies on the FTC in allowing qualified health claims on product labels.

Third, FDA's reliance on the Federal Trade Commission's (FTC) approach to health claims in advertisements in allowing qualified claims on product labels is misplaced. The FTC itself, in its *Enforcement Policy Statement for Food Advertising (EPS)*,[5] clearly distinguishes its authority under the Federal Trade Commission Act from that of the FDA. With the enactment of the NLEA, the FTC acknowledges that FDA was granted an "expanded and unique" jurisdictional mandate, which gives its regulations a "broader purpose" than just preventing false and misleading claims. The FDA is also charged with educating consumers about the importance of diet to health.[6] We believe that this additional authority justifies a different approach to health claims, as do the differences in consumer perception between information that appears on product labels and that which is included in advertisements.

In addition, we question FDA's assessment that the FTC has been "successful" in policing the marketplace for misleading food advertising. While the *EPS* contains a thorough discussion of what constitutes "adequate qualification" for health claims that are not supported by "significant scientific agreement," *the FTC has failed to bring a single case applying this policy, despite the fact that numerous petitions requesting Commission action in this area have been filed.*

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[3] 5 U.S.C. § 706(2)(A).
[4] *See* 21 C.F.R. § 101.14(e).
[5] *See* 59 Fed. Reg. 28388 (1994).
[6] *Id.*.

Moreover, in its guidance document, FDA cites in numerous instances a study by the FTC's Bureau of Economics, *Advertising Nutrition & Health: Evidence from Food Advertising 1977 – 1997.* This study is of limited usefulness, however, because it reviewed only print advertisements and did not include television ads, which the authors acknowledge are a bigger source of health claims.[7] In addition, the study considered only those ads that were published through the end of 1997, which encompasses just the first four years that the FDA's health claim regulations were in effect. The authors also clearly suggest that consumers were better informed in 1989 when health claims were more prevalent than after the NLEA, which greatly reduced such claims. This study, however, focuses only on the quantity of claims, and not on their quality. The proliferation of false and misleading health claims that appeared in ads and on labels through the end of the 1980s was a major factor leading to the enactment of the NLEA.

> There are more effective ways to provide consumers with diet-related information that can improve their health than allowing qualified health claims on product labels.

Finally, while AARP applauds FDA's desire to provide consumers with more diet-related information to help them improve their health, we believe that the agency is far too sanguine regarding the potential for health claims to provide this information. First and foremost, health claims are marketing messages, and like all other advertising, are aimed at getting consumers to buy particular products. By addressing only individual nutrients, these claims can undermine the enduring truth that it is overall diet, and not specific foods, which should be the focus. By highlighting individual foods and nutrients, health claims have the distinct potential to create the impression that individual nutrients are "magic pills," when this is clearly not the case.

To the extent that FDA is concerned that consumers do not have ready access to important nutrition information, we urge the agency to undertake a comprehensive review of newspaper, magazine, and television coverage of major nutrition-related research. We are confident that this coverage is relatively widespread, and that these media provide greater opportunities than product labels and advertisements to present a balanced, comprehensive discussion of diet-related scientific research – particularly when that research is preliminary.

AARP believes that there are better ways for FDA to provide consumers with ready access to diet-related information that they could use to improve their health. One such way would be to quickly finalize the proposed rule requiring the listing of trans fat content in the Nutrition Facts panel. In addition, FDA should explore ways to revise nutrition labeling to better educate consumers about the risks of obesity. One approach could be to highlight, through bold face type or other graphic elements, the calorie content of food products. Another could be to include, adjacent to the Nutrition Facts panel, a statement such as: "The most effective way to achieve and maintain a healthy weight is to limit your caloric intake and increase your physical activity."

The remainder of our comments will focus on some of the specific questions posed by FDA.

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[7] The authors of the study contend that there are no archives that allow for systematic review of television advertisements. Such archives do exist, although they may not cover the entire time period included in the study.

Responses to Specific Questions

1. What body of scientific evidence do you think should be adequate for a qualified health claim?

As discussed above, in order to be consistent with FFDCA, the level of scientific support for a health claim should be "significant scientific agreement."

2. What types of safety concerns should be factored into FDA's decision-making?

If FDA allows qualified health claims for conventional foods, then it must require (as it does for standard health claims) that the use of the substance that is the basis of the claim be "safe and lawful" under the FFDCA. In determining the safety of the substance, FDA should consider not only the number of people who might be injured by the substance, but also the seriousness of the harm. This approach would authorize FDA to prohibit a claim for a substance that might impact relatively few people, but where the injury could be significant.

Moreover, we urge the agency to consider both the inherent safety of the substance itself as well as the potential for serious harm as a result of interactions between the substance and other products, such as prescription and over-the-counter (OTC) drugs. If FDA determines that this interaction is not serious enough to warrant prohibiting a qualified health claim, then the agency should require that the label include a warning that alerts consumers to the potential problem.

4. On what issues are disclaimers valuable, or not valuable, in preventing consumers from being misled, and do you have data to support your view?

For a thorough response to this question, we direct FDA to comments we filed in Docket 02N-0209 in September 2002, relating to First Amendment issues. We are submitting a copy of those comments and the studies cited therein along with these comments. Our review of legal, social science and marketing research found that practical consumer experience with disclaimers and similar qualifying language calls into question whether such language does what it is intended to do: eliminate misleading impressions and remedy consumer confusion.[8]

We urge the agency to examine the theory of "information overload," which suggests that, when faced with an overabundance of data, consumers will completely ignore most or all of the information presented to them. In addition, FDA should look at the FTC's use of "affirmative disclosures" in advertising. At least one study relating to ads for OTC drugs concluded that the disclosure statements developed by the FTC would be widely misunderstood by large segments of the population.[9]

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[8] *See Pearson*, 164 F.3d at 659-60, where the court acknowledges that a health claim could be prohibited when empirical evidence demonstrates that a qualifying statement is insufficient to protect consumers from deception.

[9] *See* Jacob Jacoby et al., *Corrective Advertising and Affirmative Disclosure Statements: Their Potential for*

While Commission-sponsored research relating to health claims suggests that "strong disclaimers" – explicit references to inconsistent study results or ongoing scientific debate – have the greatest impact on consumer perceptions of the level of proof underlying a health claim,[10] our own research found otherwise. In 2002, AARP conducted an omnibus telephone survey. Respondents were read two different claims:

> "Increased consumption of foods like grape juice that are rich in antioxidants may reduce the risk of some cancers;" and
>
> "Preliminary evidence suggests that increased consumption of foods like grape juice that are rich in antioxidants may reduce the risk of some cancers but further research is necessary."

They were then asked to compare the two claims in terms of the level of scientific support. Remarkably, 52 percent of respondents thought that the second claim (which included the type of "qualifying language" that the FTC suggests is acceptable) was supported by more scientific evidence than the first, with 16 percent believing the opposite, and 22 percent thinking that the claims had the same level of scientific support. This perplexing result demonstrates the need for further research in this area.

FDA should also examine the use of qualifying language, in the form of disclaimers, in other areas, such as trademark law. A recent review of trademark disclaimer cases found that, in those cases in which disclaimers were examined empirically, they generally were found to be ineffective at alleviating consumer confusion.[11] (See attached comments and study documents for further discussion.)

5. What kinds of empirical data should FDA rely upon to show that consumers are, or are not, mislead by claims?

If FDA approves qualified health claims for conventional foods, then we believe it is appropriate to require that the party seeking approval of the claim provide empirical evidence that the specific disclaimer would eliminate any consumer confusion. As the FTC has cautioned, "it is important to recognize . . . that subtle changes in the wording or placement of claims and qualifying disclosures could have a significant impact on consumers' understanding."[12]

Confusing and Misleading the Consumer, 46 Journal of Marketing 61 (1982)..

[10] Bureaus of Economics and Consumer Protection, Federal Trade Commission, *Generic Copy Test of Food Health Claims in Advertising* at E8 (1998).

[11] Jacob Jacoby and Maureen Morrin, *"Not Manufactured or Authorized by . . .": Recent Federal Cases Involving Trademark Disclaimers*, 17 Journal of Public Policy and Marketing 97, 14 (electronic version)(1998).

[12] Press Release, "FTC Releases the Food Copy Test Results." (Nov. 18, 1998).

In trademark cases, courts were initially reluctant to rely on consumer survey evidence in arriving at their decisions, but in recent years appear to have increased their reliance on such evidence. [13] Also, the court in the *Pearson* case acknowledges that empirical evidence has a role to play in determining the effectiveness of disclaimers and disclosures.[14]

We urge FDA to require that a specific qualified claim be tested on real consumers in real-life situations before it is approved. FDA should review the testing methods used in various areas (*e.g.*, FTC and trademark cases) and identify acceptable testing methodologies. We also believe that any proposed qualified claim should be tested on a wide range of consumers – including those of different ages and different educational levels.[15]

6. Should conventional foods and dietary supplements be treated the same or treated differently, and why?

The NLEA gave FDA the authority to choose an appropriate standard for health claims for dietary supplements, and the agency's decision to apply the same standard to supplements as it does to conventional foods ("significant scientific agreement") was struck down in court. As a result, dietary supplement labels can currently include "qualified" health claims.

Rather than having a standard for health claims that is more permissive than that used for conventional foods, we believe that at least some dietary supplements products – those that pose safety problems – should have a *stricter* health-claim standard. For example, we believe that it would clearly be misleading to allow an ephedra product to include a health claim, such as "reduces the risk of obesity," on its label. The safety risks associated with this product are definitely related to its health benefit and must be factored into a decision regarding whether to allow a health claim on the product label. In this example, the safety risks of the product outweigh the health benefit, and therefore a health claim should not be allowed. Moreover, ephedra's risks are so serious that the addition of qualifying language or other disclaimers would not be sufficient to eliminate the misleading impression created by the claim.[16]

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[13] Jacob Jacoby and Maureen Morrin, *"Not Manufactured or Authorized by . . .": Recent Federal Cases Involving Trademark Disclaimers*, 17 Journal of Public Policy and Marketing 97, 14 (electronic version)(*citing* Jacob Jacoby, "Survey and Field Experimental Evidence," in The Psychology of Evidence and Trial Procedure, Saul M. Caisson and Lawrence S. Wrightsman, eds., Beverly Hills, CA: Sage Publications, 175 -200 (1995)).

[14] *See* 164 F.3d at 659-60.

[15] *See* Christine Moorman and Linda L. Price, *Consumer Policy Remedies and Consumer Segment Interactions,* 8 Journal of Public Policy & Marketing 181 (1989)(we need to look not just at the costs and benefits but also at the distributional effects of an information remedy on specific consumer segments).

[16] This is consistent with the *Pearson* decision, in which the Court identified situations when FDA would not be required to allow a qualified health claim, including when the product would threaten consumer health and safety.

Ephedra is a clear example of a dangerous supplement. However, reliance on misleading, inaccurate health claims can also harm consumers in less direct and immediate ways. A consumer may reject a proven treatment for a disease or health-related condition and, instead, choose a particular food or supplement product based on an inadequately substantiated claim about its ability to prevent or treat the particular condition. If the product chosen by the consumer does not, in fact, perform as claimed, the consumer, at the very least, will be harmed economically. At the very worst, his health and safety may be seriously jeopardized.

Reliance on misleading health claims can have a more insidious effect. Not only might consumers lose confidence in the particular product, but they may also become skeptical about all health-related information that is included on product labels and in advertisements.

The same result can occur when health claims are based on "preliminary evidence." The problem here is that all too often, "preliminary evidence" is ultimately proven wrong.[17] A 2002 report by the Institute of Medicine of the National Academy of Sciences uses the experience with beta-carotene to illustrate this problem. While an "impressive" body of evidence suggested that increased intake of foods rich in beta-carotene might reduce the risk of developing lung cancer, subsequent research suggested that increased consumption of beta-carotene actually *increased* the risk of cancer in high-risk populations.

Conclusion

AARP appreciates the opportunity to comment on this important guidance document. If you have any questions about our comments, please contact Larry White on our Federal Affairs staff (202-434-3800).

Sincerely,

David Certner
Director
Federal Affairs

[17] *See* Food and Nutrition Board, Institute of Medicine, Evolution of Evidence for Selected Nutrient and Disease Relationships 6 (2002)("An important finding is that preliminary evidence in support of a nutrient-disease relationship was often not confirmed").