GROCERY MANUFACTURERS OF AMERICA
MAKERS OF THE WORLD'S FAVORITE BRANDS OF FOOD, BEVERAGES AND CONSUMER PRODUCTS

2101 PENNSYLVANIA AVE NW
SECOND FLOOR
WASHINGTON, DC 20037
PHONE (202) 337-9100
FAX (202) 337-4508
brands.com

June 19, 2003

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

Re: Guidance on Qualified Food Disease Claims
67 Fed. Reg. 78002 (December 20, 2002)
FDA Docket No. 02D-0515

The Grocery Manufacturers of America (GMA) is the worlds largest association of food, beverage, and consumer brand companies. GMA member companies sell more than $460 billion in consumer food and other products each year and employ more than 2.5 million workers in all fifty states. GMA speaks for food and consumer brand manufacturers at the state, federal, and international levels on legislative and regulatory issues. These manufacturers have a deep interest in using truthful and nonmisleading claims for their food products.

I. GMA Agrees With the Portion of the December 2002 Guidance that Applies the Pearson Decision to Conventional Food

In a Citizen Petition submitted on April 27, 2000 and in a Disease Claims Petition submitted on March 14, 2001, GMA requested FDA to implement the court decision in Pearson v. Shalala[1] in an equal and nondiscriminatory way to both conventional food and dietary supplements. In response to the FDA request on May 16, 2002 for public comment on the

[1] 164 F.3d 650 (D.C. Cir. 1999), rehearing denied, 172 F.3d 72 (D.C. Cir. 1999) (en banc); on remand, 130 F. Supp 2d 105 (D.D.C. 2001), and on reconsideration, 141 F. Supp. 2d 105 (D.D.C. 2001).

2002D-0515

C 5

application of First Amendment principles to FDA policy,[2] GMA submitted comments strongly arguing that the First Amendment requires FDA to approve qualified disease claims for conventional food as long as they are not misleading, and that the standard for determining whether a claim is misleading must be the reasonable person rather than the ignorant, unthinking, and credulous person. These petitions and comments are hereby incorporated by reference in these comments. If you would like additional copies, we will be happy to provide them.

The new policy announced on December 18, 2002,[3] and embodied in the guidance that is the subject of the Federal Register notice on December 20, 2002,[4] responds directly to and grants the action requested in these GMA petitions and comments. Accordingly, GMA fully endorses and supports this portion of the announced new policy. GMA has, in fact, withdrawn its two petitions, because both of them requested precisely the action that FDA took on December 18. With this action, FDA has now brought this aspect of its policy respecting disease claims for conventional food into compliance with First Amendment jurisprudence.

II. "Emerging Science" Disease Claims Fall Within the New FDA Policy

GMA has repeatedly pointed out that one particularly important form of qualified disease claims for food pertains to "emerging science" about the relationship between diet and disease. As explained further below, it is GMA's interpretation of the December 2002 guidance that this area of disease information is now fully within the FDA implementation of the Pearson

---

[2] 67 Fed. Reg. 34942 (May 16, 2002).

[3] "FDA Announces Initiative to Provide Better Health Information for Consumers." FDA News No. P02-54 (December 18, 2002).

[4] 67 Fed. Reg. 78002 (December 20, 2002).

decision and its policy on qualified disease claims for all food. If this were not true, it would violate both the Federal Food, Drug, and Cosmetic Act and First Amendment jurisprudence.

In its guidance issued in December 1999 in response to the Pearson, FDA took the position that there cannot be significant scientific agreement about emerging science, and thus that no type of statement with respect to emerging science in the field of diet and disease would be approved. FDA took the position in that guidance that, to be approvable, a claim must describe a diet/disease relationship that is already established by significant scientific agreement, and cannot describe a diet/disease relationship in truthful and nonmisleading terms based upon preliminary data, or emerging science, or factual statements about the current status of scientific research, or reports on the findings and recommendations of authoritative nongovernmental scientific bodies.

By stating that the diet/disease relationship itself must be supported by significant scientific agreement, FDA has sought to impose a greater restriction on speech than Congress contemplated or than the Constitution permits. Section 403(r)(3)(B)(i) of the Federal Food, Drug, and Cosmetic Act provides unequivocally that FDA "shall" approve a disease claim if there is significant scientific agreement "that the claim is supported by such evidence." Thus, the statute requires that "the claim" be supported -- not that the diet/disease relationship be supported -- by significant scientific evidence. Moreover, the Pearson decision and related First Amendment jurisprudence makes clear that FDA cannot disapprove a disease claim about emerging science that is truthful and nonmisleading.

As GMA understands the December 2002 Guidance, FDA has adopted this approach. FDA has chosen to establish approval of an emerging science claim under a new

system for qualified disease claims rather than under a system for significant scientific agreement claims. This is a matter of semantics. An emerging science claim would necessarily be qualified and explained in order to make it truthful and nonmisleading. Whether it is approved as a qualified disease claim or as a significant scientific agreement disease claim is therefore immaterial. Only if FDA were to take the position that these claims cannot be approved under any circumstances would GMA again assert its long-established position that such action would violate both the statute and the First Amendment.

III. The "Weight-of-the-Evidence" Standard Proposed By the December 2002 Guidance Does Not Comply With First Amendment Requirements

The December 2002 guidance on qualified food disease claims states, as one of the four requirements for FDA approval of a qualified disease claim, that:

> "(2) the scientific evidence in support of the claim outweighs the scientific evidence against the claim, the claim is appropriately qualified, and all statements in the claim are consistent with the weight of the scientific evidence;"

As demonstrated by the most recent decision in the ongoing Pearson litigation (Whitaker v. Thompson,[5] which was handed down after the December 2002 FDA policy announcement), this standard fails to meet the First Amendment test imposed by Pearson.

As the Whitaker decision pointed out, the Pearson opinion identified only two situations in which a complete ban would be reasonable: where no evidence supports a disease claim or where the evidence in support of the claim is qualitatively weaker than evidence against the claim, e.g., where the claim rests on only one or two old studies.[6] Even in those two

[5] Whitaker v. Thompson, D.D.C. Civ. No. 01-1539 (GK) (December 26, 2002).

[6] Slip opinion at 21.

situations, a complete ban would be appropriate only when "the government could demonstrate with empirical evidence that disclaimers . . . would bewilder consumers and fail to correct for deceptiveness."[7] Accordingly, the district court concluded that under the Pearson decision:

> ". . . any complete ban of a claim would be approved only under narrow circumstances, i.e., when there was almost no qualitative evidence in support of the claim and where the government provided empirical evidence proving that the public would still be deceived even if the claim was qualified by a disclaimer."[8]

Of particular importance, the court explicitly rejected the FDA "weight-of-the-evidence" standard. First, the court concluded that the FDA standard did not comply with the Pearson decision:

> "The FDA has banned the Plaintiffs' claim by concluding that the evidence in support of it was weaker than evidence against it, but it is clear that more than 60 recent studies reviewed by the FDA supported the claim. This hardly constitutes the 'one or two old studies' that the Court of Appeals contemplated might support a total ban."[9]

Second, even if the FDA standard were accepted, the agency failed to present empirical evidence that a disclaimer or other explanatory information would be inadequate to make a qualified disease claim truthful and nonmisleading:

> ". . . even if the FDA's decision to ban the Claim could be justified by finding that the evidence in support of it was clearly qualitatively weaker than the evidence against it, the FDA has failed to provide empirical evidence that an appropriate disclaimer would confuse consumers and fail to correct for deceptiveness."[10]

---

[7] Id.

[8] Slip opinion at 22.

[9] Slip opinion at 28-29 (emphasis is in original).

[10] Slip opinion at 29.

Accordingly, the district court remanded the matter to FDA for preparation of appropriate disclaimers to accompany the disease claim involved in that litigation.

The standard adopted in the December 2002 FDA guidance on disease claims therefore violates the First Amendment, as determined by the District of Columbia courts, in two respects. First, it fails to recognize that any credible scientific evidence is sufficient to support a qualified disease claim, regardless whether it satisfies the weight-of-the-evidence test. Second, it fails to recognize that a qualified disease claim that is supported by credible scientific evidence must be approved unless FDA can demonstrate by empirical evidence that consumers are incapable of understanding it. GMA urges FDA to withdraw both the December 1999 guidance and the December 2002 guidance and to issue a new guidance that incorporates the correct First Amendment standard for qualified disease claims as established in the Pearson litigation.

IV. Conclusion

For the reasons set forth above, GMA applauds FDA for its initiative to provide better health information to consumers and urges the agency promptly to adopt a new guidance that conforms the standard for FDA approval of qualified disease claims to the First Amendment jurisprudence established in the Pearson litigation..

Sincerely yours,

Alison J. Kretser
Director of Scientific
and Nutrition Policy

James H. Skiles, Esquire
Vice President and General Counsel