Kraft Foods

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January 16, 2006

Division of Dockets Management
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, Maryland 20852

Re: Docket No. 2005N-0413
Assessing Consumer Perceptions of Health Claims
Notice of Public Meeting; Request for Comments
70 Fed. Reg. 60749 (October 19, 2005)

Dear Sir or Madam:

Kraft Foods Global, Inc. (Kraft) is a $32 billion company, the largest food manufacturer in North America, and the second largest worldwide. For over 100 years, Americans have trusted the well-known brands Kraft sells. Today, Kraft brands are found in more than 99% of all U.S. households and over 155 countries around the world.

Kraft's strong and enduring relationship with consumers is founded on clear and effective communication of product attributes, including nutrition and health benefits. We continually strive to improve this communication and, consequently, have extensive experience evaluating and refining methods for conveying information to consumers.

FDA's recently released study "Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claims" adds to a growing body of research about consumers' perception and understanding of health claims. Other recent studies in this area include the Federal Trade Commission's "Consumer Perceptions of Qualified Health Claims in Advertising,"[1]; the International Food Information Council's (IFIC) "Qualified Health Claims Consumer Research Project Executive Summary"[2]; France and Bone's "Policy Makers'

[1] Murphy, R. Dennis, "Consumer Perceptions of Qualified Health Claims in Advertising," Bureau of Economics, Federal Trade Commission (July 2005).

[2] "Qualified Health Claims Consumer Research Project Executive Summary," International Food Information Council (March 2005).

Paradigms and Evidence from Consumer Interpretations of Dietary Supplement Labels"[3]; and Hooker and Teratanavat's "Qualified Health Claims: Food for Thought?"[4]

This research consistently reveals the serious shortcomings of a "fixed language" approach to expressing health claims. It confirms what our experience and insight with respect to effective consumer communication tell us—boilerplate qualifiers (e.g., "promising but not conclusive", "limited and inconclusive") tied to preconceived "levels" of scientific support do not help consumers understand the often complex relationships between food substances and specific health conditions. We know from our experience with consumers that boilerplate language produces an "eyes glaze over" response that reduces the likelihood subtle differences in the words of different fixed language statements will be noticed or understood. In fact, formulaic expressions may actually mislead consumers.

Consumer friendly "plain" language best communicates health-related information to the general population. To communicate effectively, the wording of each claim must be tailored to the facts about the specific substance/disease relationship at hand. For example, the maturity and robustness of the scientific evidence, the class of people who may benefit (e.g., women and osteoporosis), and the kind of diet that must be followed (low in saturated fat) are the types of facts that may be important to a clear statement of the claim.

Communication testing by qualified experts can help ensure that consumers are not misled by the phrasing of the claim. Claims stated in simple language and founded on well-accepted science may not require communication testing in every case, but less certain claims describing more complex relationships may need the support of such testing to clear the agency's review process.

Simple, science-driven language can do little to improve public health, unless it is available to consumers in a timely way. To ensure that substance/disease information reaches consumers promptly, we urge the agency to create a permanent notification procedure for assessing health claims. This procedure would put the burden of collecting, reviewing, evaluating, and presenting the scientific evidence and of conducting necessary consumer communication research directly on the proponent of the claim. As FDA implicitly concluded in setting up the interim review process for examining "qualified health claims," without an alternative to full notice and comment rulemaking, the agency is unlikely to satisfy the demands of the First Amendment or make meaningful practical progress against the central goal of its Consumer Health Information for Better Nutrition Initiative (CHIBNI).

[3] France, K.R. and Bone, P.F., "Policy Makers' Paradigms and Evidence from Consumer Interpretations of Dietary Supplement Labels," The Journal of Consumer Affairs, Vol. 39, Number 1 (Summer 2005).

[4] Hooker, N.H. and Teratanavat, R.P., "Qualified Health Claims: Food for Thought?", Department of Agricultural, Environmental, and Development Economics, The Ohio State University (October 2005).

Pearson and CHIBNI Give FDA a Unique Opportunity
to Improve the Review and Communication of All Health Claims

It is important to note at the outset that the current focus on consumer perception of health claims is a direct outgrowth of the courts' decisions in *Pearson* and succeeding commercial speech cases. These cases bar FDA from banning health claims for foods unless it can make an empirical showing that a disclaimer or other qualifying statement would not cure the potential for a misleading impression among consumers.[5]

The demands *Pearson* places on the agency have given FDA a unique and important opportunity. In the context of responding to *Pearson*, the agency can consider how it regulates all health claims to ensure that its review of substance/disease relationships is efficient, science-driven and results in claims that accurately convey the nature and limits of the underlying scientific support to consumers. We urge FDA to explore this opportunity to its fullest advantage.

We stress that this effort should include all health claims. In our view, any distinction between qualified health claims (QHCs) and significant scientific agreement (SSA) claims is purely artificial, not one on which FDA or consumers should focus. The distinction is an artifact of the circumstances that led to *Pearson*, incorporated by the agency into its interim QHC policy, and thus related solely to agency procedure. All health claims, including those that meet the SSA standard, are and need to be qualified (e.g., "may reduce the risk of"; "as part of a diet low in saturated fat and cholesterol"), and certainly the demands of the First Amendment are the same regardless of what term is used to describe a claim or category of claims. The agency's revised regulatory approach should reflect this reality and apply to all disease-related health claims.

Predetermined Phrases Cannot Accurately or Effectively Describe the Complex Science
Underlying Substance/Disease Relationships

We agree with FDA that a full reconsideration of the agency's approach to regulating health claims should include available information about consumers' perception of health messages on the food label. The research to date, however, only confirms what we see as a critical problem—the agency's tentative conclusion that the scientific evidence underlying the vast universe of real and potential substance/disease relationships can and should be assigned to a finite number of levels and that a generic phrase, "easily understood by consumers," can be developed to describe all of the relationships in those levels (e.g., "promising but not conclusive", "limited and inconclusive"). The studies cited earlier seem to assume the validity of this conclusion rather than test whether it is, in fact, accurate.

[5] *Pearson v. Shalala*, 130 F. Supp. 2d 105, 118 (D.D.C. 2001) (citing *Pearson v. Shalala*, 164 F.3d at 658); *Whitaker v. Thompson*, 248 F. Supp.2d 1, 10-11 (D.D.C. 2002).

The scientific data supporting every substance/disease relationship are unique and, thus, cannot be accurately conveyed by rigid, predetermined phrases. The difficulties consumers experienced in all of the studies differentiating among predetermined phrases convinces us that a system built on this foundation will not benefit consumers.

We doubt, moreover, whether "one size fits everything in the category" labeling is compatible with the demands of the First Amendment. The decision in *Pearson* and in every succeeding case in that line turned on application of the third prong of *Central Hudson* (i.e., whether there is a reasonable fit between the government's stated goal and the means chosen to accomplish that goal).[6] In each instance, the court examined the science supporting the particular substance/disease relationship at issue in deciding whether the FDA's actions were consistent with the First Amendment.[7]

We note as well that, in designing the provisions for approval of SSA health claims under the Nutrition Labeling and Education Act (NLEA), Congress did not rely on predetermined claim language. Likewise, FDA's regulations implementing Section 403(r)(3)(B) carefully avoid any prejudgment of the language appropriate to communicate SSA claims.

Rather than ignore this precedent and struggle to shoehorn the complex world of emerging science into a few stock phrases, we urge the agency to address the question of claim language flexibly—allowing the science relating to each substance/disease relationship to determine the specific language used to express the relationship on the food label. This approach will avoid the arbitrary nature of predetermined labels and, in so doing, better reflect the courts' direction in *Pearson* and the cases that followed. It also seems far more likely to succeed in practice. A system driven by categories and predetermined labels will almost certainly lead to long, unconstructive debates about the "correct" category for a substance/disease relationship.

Creating a Notification System Would Benefit Public Health by Promoting More Timely Release of Health-Related Information on the Food Label

An approach driven by science rather than predetermined labels requires a regulatory process that places the burden of gathering, reviewing, organizing, ranking, and summarizing the relevant scientific data squarely on the party seeking to make the health claim. The notice and comment petition process and the interim qualified health claims review process in place today

[6] *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980).

[7] *See Pearson v. Shalala*, 164 F.3d 650, 658-59 (D.C. Cir. 1999); *Pearson v. Shalala*, 130 F. Supp. 2d 105, 114 (D.D.C. 2001); *Pearson v. Thompson*, 141 F. Supp. 2d 105, 109 (D.D.C. 2001); *Whitaker v. Thompson*, 248 F. Supp. 2d 1, 11-13 (D.D.C. 2002).

drain agency resources and, in our estimation, delay the release of valuable health-related information to consumers.

We recommend that the agency add a structured notification and substantiation process—open to proponents of all substance/disease health claims—to the existing notice and comment petition route for SSA claims. Under such an approach, the burden would fall on the notifying company to gather, review and present the evidence supporting or undermining a substance/disease relationship. Additionally, we envision that the proponent would engage experts qualified by training and experience to peer-review the evidence and provide summary recommendations supported by the underlying data for FDA's consideration. This peer-review step, analogous to the process often used in making GRAS determinations, would be a new requirement that would vastly improve the quality of the scientific information the agency receives, allowing it to speed its review and focus its limited nutrition science resources more productively for the benefit of consumers.

The notification and substantiation process we envision would permit companies interested in making a claim about a substance/disease relationship that is not already specifically permitted by regulation (or pursuant to the interim enforcement discretion procedures) to submit a comprehensive package to FDA at least 180 days before making the claim in interstate commerce. The notification and substantiation data would include a number of mandatory elements, the most significant of which would be:

- A concise description of the scientific evidence supporting the substance/disease relationship;

- A balanced description of the scientific literature supporting and contradicting the substance/disease relationship.

- The findings of a review panel composed of scientific experts qualified by training and experience to peer-review the evidence. The panel's findings would include:

    - A description of the panel members' individual credentials establishing them as "experts" in the field.
    - A narrative description of the relevant studies, as well as the panel's classification and ranking of the studies in accordance with the principles set forth in the agency's "Interim Evidence-Based Ranking System for Scientific Data" (July 2003).
    - A concise description of the panel's overall conclusions with respect to the strength of the science underlying the substance/disease relationship and

its confirmation that the language chosen by the submitter to articulate the relationship is supported by the science.

- The exact words of the claim the submitter plans to make, including any disclosures or qualifying statements to ensure that the claim is truthful and not misleading.

- Evidence that consumers would not be misled by the language of the claim.[8]

We propose that FDA would have 180 days to review a notification. Any notification that did not contain all of the mandatory elements would be rejected immediately as "incomplete." Consistent with current interim procedures, "complete" notifications would be published as soon as practical for public comment.[9] Based on comments received, as well as the agency's own evaluation, FDA would permit the 180-day period to expire without objection, at which point the proponent would be free to begin using the claim, or issue a letter of objection.

Letters of objection would describe why FDA believes the conclusions drawn by the submitter and/or the scientific review panel are inappropriate as a matter of science or why the language chosen by the submitter inaccurately conveys the nature or strength of the substance/disease relationship. Submitters who receive letters of objection (or, who anticipate receiving them as a result of communications with FDA staff) would have the opportunity to resolve their differences of opinion with the agency.

FDA would have ample authority under Sections 403(a) and 201(n) of the Act to ensure that no submitter moved forward to use a claim without first resolving agency objections or concerns. FDA would retain this authority even after the 180-day review period had lapsed. Any significant change in circumstances relating to the claim (e.g., OFAS questions whether the substance is safe at the levels need to support the claim; additional scientific evidence becomes available that negates the evidence relied on by the submitter; or consumer communication research demonstrates that consumers are misled by the claim) would constitute reasonable grounds for exercise of this authority.

A Notification Option is Supportable for All Health Claims

We acknowledge that a notification and substantiation process open to all health claims may look inconsistent with Section 403(r)(3) of the Act, which seems to contemplate traditional

[8] FDA might well conclude that some or all notifications should be supported by the results of consumer research conducted in accordance with protocols and methodologies typically used and accepted by the Federal Trade Commission.

[9] Consistent with the existing interim procedure for qualified health claims and 21 C.F.R. § 101.70, data and information submitted in connection with all notifications would be available for public review.

notice and comment approval for SSA health claims. Several considerations convince us, however, that a notification system is fully supportable for all health claims.

First, the existing notice and comment system for SSA claims (i.e., 21 C.F.R. §§ 101.4 and 101.70) would be retained side-by-side with the new notification process, giving companies the option to choose either route for an SSA claim and ensuring that the literal language of Section 403(r)(3) continues to be given effect.[10]

Second, although Section 403(r)(3) states that the Secretary "shall" promulgate regulations authorizing health claims, and further states that disease claims "may only be made" if they meet the requirements of those regulations, FDA retains discretion not to take enforcement action against nonmisleading health claims that lack authorizing regulations. In fact, FDA is relying upon this very authority today in permitting the use of reasonably supported QHCs. Surely, a plausible reading of the Act would permit SSA health claims that are not the subject of a specific regulation, particularly if those claims are supported by a well-substantiated notification.

Third, although 403(r)(3) remains in the Act, Congress evidently does not believe notice and comment rulemaking is an essential prerequisite for responsible use of health claims. Only six years after enacting 403(r)(3), it chose notification to implement FDAMA health claims. The notification system we are proposing is a close approximation of the FDAMA system. The findings of the scientific panel would play essentially the same role as the authoritative statement by the National Academy of Sciences or other government body with responsibility for public health.

Finally, and no doubt most significantly, good public policy demands a system that is founded on notification and that is consistent for both SSA claims and QHCs. Kraft agrees fully with CHIBNI's conclusion that consumers will benefit from more diet and health information on food labels. Realizing those benefits, however, requires a system that allows companies to bring this information to consumers' attention in a timely, efficient manner. The processes currently in use for reviewing health claims need dedicated agency resources that are not available now and are unlikely to become available in the foreseeable future.

In short, we urge FDA to act decisively on CHIBNI's recommendations to provide more health-related information to consumers by establishing a notification and substantiation process

[10] We suspect that many proponents of SSA claims would continue to seek approval of their claims via the notice and comment petition route, given the greater regulatory certainty that route would provide. As discussed at greater length above, FDA would be free at any time to take enforcement action against proponents of notified claims if a change in circumstances or additional data convinced FDA that the claims were no longer truthful and nonmisleading. In contrast, FDA would have to go through notice and comment rulemaking to revoke or modify an SSA claim approved through the existing petition route.

and to do so for all health claims. A two-tier system—one path for SSA claims, another for QHCs—that effectively imposes less process and delay on claims that are supported by weaker evidence, as the current system does, defies reason. The constitutional standards the agency must meet in regulating SSA claims and QHC are the same; the regulatory procedures for making the claims should be as well.

* * * *

We appreciate the agency's continuing commitment to enhancing the communication of health-related information to consumers. Better, more timely dissemination of substance/disease information has enormous potential for improving public health. At the same time, *Pearson* and CHIBNI have given FDA a unique opportunity—the opportunity to improve the review and communication of all health claims.

We urge the agency to begin this effort by critically reexamining its untested assumption that a few predetermined phrases can fully and accurately convey the complex nuances of substance/disease relationships. In our view, accurate communication of substance/disease information demands a less prescriptive approach, directly tailoring the language used to convey a relationship to the scientific evidence that underlies it. Timely communication of that information to consumers—a central tenet of CHIBNI—demands an alternative review process. To us, notification, with the assurance of competent peer-review, is the appropriate choice.

We appreciate the opportunity to comment on this initiative and look forward to working cooperatively with FDA as the agency strives to fulfill all the demands placed upon it during a time of significant resource constraints.

Respectfully submitted,

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