



John Ruff
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February 25, 2004

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

Re: Food Labeling: Health Claims; Dietary Guidance; Advance Notice of Proposed Rulemaking; 68 Fed. Reg. 66040 (Nov. 25, 2003)

Dear Sir or Madam:

For over 100 years, Americans have trusted the well-known brands Kraft Foods (Kraft) sells. Today, our brands are found in more than 99% of all U.S. households and are sold in 150 countries around the world. Kraft is a \$30 billion global company, the largest food manufacturer in North America, and the second largest worldwide. We distribute over 18 billion packages of food each year. Therefore, our interest in the regulation of claims on food labels is substantial.

In commenting upon the Advance Notice of Proposed Rulemaking (ANPR), we are especially aware that the trust we have built over the last 100 years is priceless and critical to our continued success. In short, we share the government's interest in the credibility of the food label.

Kraft is concerned that the current focus on the First Amendment right to make so-called "qualified" health claims misses two fundamental points: first, all health claims are in a very real sense qualified; and second, all claims on food labels are protected equally under the First Amendment, provided of course that no claim may be false or misleading. If consumers are to rely on food labels, every health claim, whether deemed "qualified," the statement of an "authoritative body," or the subject of "significant scientific agreement", should be supported by credible, competent and reliable, scientific evidence. In other words, health claims should be supported by the type of scientific evidence upon which qualified experts would rely for accurate results. Every claim also should be communicated in a context that will not mislead reasonable consumers.

The regulatory options suggested in the ANPR all have one troublesome characteristic in common: claims that are "qualified," due to inherent limitations

in the supporting scientific evidence, would be cleared by FDA much faster than well-supported claims that are the subject of “significant scientific agreement”. If a claim is supported by “significant scientific agreement”, a time consuming notice and comment rulemaking process applies; but “qualified” claims, which frequently are the subject of scientific debate and uncertainty, would undergo a less burdensome notification process estimated to take half the time. Logically, a properly prepared, well-substantiated petition for a “significant scientific agreement” health claim should merit prompt FDA review and clearance. Adopting a “less burdensome” regulatory scheme for “qualified” claims that effectively encourages use of scientifically weaker claims hardly seems sound from a policy perspective.

Whether the distinction between “qualified” and “significant scientific agreement” claims is clear enough to be a practical basis for funneling claims into different pathways for FDA review is at best debatable. Health claims routinely and necessarily incorporate “qualifying language” (like “among women” or “following a low saturated fat diet”), so the plain language of the claim alone is not dispositive. Reasonable people can reach different conclusions about whether a claim is the subject of “significant scientific agreement” or “almost significant scientific agreement”. Indeed, as of the time a notice or petition is filed, it can be very difficult to predict whether or not FDA ultimately will conclude the claim is supported by “significant scientific agreement”—the determination which controls whether or not the claim is considered “qualified” for regulatory purposes.

We see the potential for the pre-market screening process debate to cloud the important substantive questions about what health messages convey reliable information that will benefit the public. From our point of view, industry and FDA resources should be directed toward facilitating clearance of well-substantiated and appropriately qualified claims. Consumers have no knowledge---and need no knowledge---of the procedural intricacies governing claims clearance at FDA. Instead, consumers need reliable claims communicated in a context that accurately portrays the existing level of scientific support.

To facilitate the availability of “more and better information” about the health benefits of food products,¹ Kraft urges FDA to take the following actions:

- 1) encourage the communication of well-founded and properly-qualified health claims by using the interim rulemaking authority;
- 2) confirm that “credible” evidence means competent and reliable evidence—“tests, analyses, research, studies, or other evidence based

¹ Consumer Health Information for Better Nutrition Initiative, Task Force Final Report (July 10, 2003) (emphasizing the need for consumers to have improved access to more and better health information).

on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate results”;² and

- 3) recognize the importance of flexibility in claims communication by abandoning the confusing standard disclaimer language adopted for the interim approach to “qualified” claims regulation.

When results of the communication testing now in process become available, the additional research being conducted by FDA and industry should help to guide development of a sound regulatory approach.

1. The Interim Rulemaking Process—An Incentive for Claims Based on Significant Scientific Agreement

The interim rulemaking authority Congress granted to FDA in the Food and Drug Administration Modernization Act of 1997 (FDAMA)³ provides a way for FDA to retain the proper focus on the most well-substantiated claims with the greatest potential to benefit the public. Under section 403(r)(7) of the Federal Food, Drug, and Cosmetic Act, as amended by FDAMA, FDA has broad authority to make proposed health claim regulations immediately effective upon publication in the *Federal Register*, subject to public comment and further review. FDA may use its interim rulemaking authority under section 403(r)(7) when the rapid dissemination of health or nutrient content claims will promote healthy dietary practices, facilitate the availability of important health or nutrition-related findings, or ensure that scientifically sound information is available to consumers as soon as possible. Significantly, these objectives are precisely the intent of the Consumer Health Information for Better Nutrition Initiative. Now that Congress has given FDA authority to adopt interim final rules in appropriate cases, FDA should presumptively use that streamlined process, unless there are clear reasons to use the longer notice and comment rulemaking process.

At present, “significant scientific agreement” claims are paradoxically required to undergo a far longer review period than is contemplated under the interim review policy for “qualified” claims. As shown in the table below, the review period for significant scientific agreement claims, 540 days, is twice as long as the 270-day planned review time for “qualified” claims. This discrepancy actually encourages industry to propose “qualified” claims, even if a very similar claim might reach the “significant scientific agreement” threshold.

² 68 Fed. Reg. at 66045 (citing *In Re: Great Earth Int'l, Inc.*, 110 F.T.C. 188 (1988)).

³ FDAMA § 301.

Type of Claim	Maximum Time to Authorization	Additional Details
Health claim based on "significant scientific agreement"	540 days	<ul style="list-style-type: none"> ▪ 100 days for filing ▪ 90 days to publish proposal ▪ 270 days to publish final rule ▪ Up to 180 days to extend time period for final rule, not to exceed a total of 540 days ▪ Extensions as mutually agreed upon by FDA and the petitioner
"Qualified" health claim	270 days	<ul style="list-style-type: none"> ▪ 45 days for filing ▪ 60 days for public comment ▪ 270 total days ▪ Extensions as mutually agreed upon
Health claim authorized by interim final rulemaking	190 days	<ul style="list-style-type: none"> ▪ 100 days for filing ▪ 90 days to publish proposal and authorization for immediate use pending final rule ▪ Extensions as mutually agreed upon

As these timeframes illustrate, if FDA were to rely on its interim rulemaking authority, manufacturers could expect to use claims within 190 days of submission (or longer, if extensions are granted). A review period of this length would provide an important incentive for industry to pursue "significant scientific agreement" claims.

In the ANPR, FDA expressed concern that routine reliance on the interim rulemaking process might create an unfair marketing advantage, if FDA were to inappropriately characterize a substance or misinterpret the publicly available scientific evidence. Yet the interim rulemaking authority has been used successfully in three instances.⁴ In two of the three examples cited in the ANPR,

⁴ 65 Fed. Reg. 54686 (Sept. 8, 2000) (plant sterol/stanol esters and reduced risk of coronary heart disease (CHD)) (final rule forthcoming); 67 Fed. Reg. 61773 (Oct. 2, 2002) (beta-glucan soluble fiber from whole oat sources and reduced risk of CHD) (adopted without change, 68 Fed.

no changes were made at the final rule stage; in the third, a final rule that will address public comment is pending. If the agency concludes that the interim rulemaking authority should not be used in a specific case, the agency would retain the option to follow traditional notice and comment procedures. Additionally, enforcement discretion always remains an option.⁵ In keeping with the spirit of the Consumer Health Information for Better Nutrition Initiative, Kraft believes considerable health benefits could be obtained from increased application of interim rulemaking authority.

2. Credible evidence

FDA requests comment on the “meaning and/or relevance of ‘competent and reliable scientific evidence’ for the purposes of supporting a qualified health claim.” Kraft concludes that “credible evidence” is necessarily “competent and reliable.” In our view, this means that the evidence used to support a “qualified” health claim is of a type and amount that would be judged adequate by qualified experts to support the message conveyed in the claim.

Kraft submits that credibility must be assessed both in the context of individual studies and in light of the overall degree of scientific support suggested by the claim. For example, if it is claimed that “emerging studies suggest” a particular substance-disease relationship, there should be credible evidence sufficient to convince qualified experts that multiple preliminary studies do in fact support the claimed relationship. The individual studies supporting the claim must be competent and reliable; that is, they must consist of “tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate results.”⁶ Further, these studies must be evaluated in the context of the entire body of relevant evidence, particularly if the results are contrary to that body of evidence.

3. Flexibility

As discussed above, all health claims must be supported by adequate science, and priority should be given to review of those claims for which the level of scientific support and potential public health benefit is the greatest. Where the

Reg. 44207 (July 28, 2003)); 67 Fed. Reg. 71461 (Dec. 2, 2002) (D-tagatose and dental caries) (adopted without change, 68 Fed. Reg. 39831 (July 3, 2003).

⁵ FDA Letter Regarding Enforcement Discretion With Respect to Expanded Use of an Interim Health Claim Rule About Plant Sterol/Stanol Esters and Reduced Risk of Coronary Heart Disease (Feb. 14, 2003).

⁶ 68 Fed. Reg. at 66045 (citing *In Re: Great Earth Int'l, Inc.*, 110 F.T.C. 188 (1988)).

state of the science has not yet reached “significant scientific agreement,” and a “qualified” health claim is appropriate, flexibility is needed to ensure that the level of available support is appropriately expressed in the claim. Identifying possible qualifying language for the universe of health claims on a prospective basis is simply unrealistic.

At Kraft, our experience suggests consumers have difficulty distinguishing among more than three levels of scientific support. In recent focus group research sponsored in part by Kraft, consumers had difficulty distinguishing among the B-, C-, and D- level qualifiers suggested by FDA and were unable to rank these claims reliably according to the relative strength of the underlying scientific evidence. Additionally, having seen B-, C-, and D-level claims with their explicit identification of supporting evidence, several consumers rated A-level claims as comparatively weaker because no supportive evidence was mentioned. This research suggests that the present use of 4 categories of health claims is confusing to consumers, particularly as to the C- and D-level claims. Furthermore, a troubling aspect of this research indicates that when consumers see a letter grade ranking of a health claim on package, they tend to interpret this as an evaluation of overall product quality.

A qualitative assessment of the four claim categories presented in the interim policy suggests that the distinction between “limited and not conclusive evidence” (the existing C-level claim) and “very limited and preliminary scientific research” (the existing D-level claim) is too fine for most consumers to appreciate. A better plan would be to develop a comprehensive approach that places all health claims into one of three categories of scientific support, as follows: (1) “significant scientific agreement”, (2) evidence that “suggests, but does not prove”, and (3) “preliminary evidence”. Any standard consumer-friendly language used to communicate evidence falling into one of these categories should be based upon appropriate consumer testing. For example, as part of the approval process for the recent health claim for nuts, considerable research demonstrated that consumers could properly comprehend the level of scientific support for the claim based on alternative presentations of the message. Kraft recognizes that there may be value to establishing model “safe harbor” language for characterizing the applicable level of scientific data supporting a health claim, as long as equivalent language also is permitted.

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In summary, Kraft recommends industry and FDA resources be directed toward facilitating clearance of well-substantiated and appropriately qualified claims. Furthermore, Kraft recommends FDA recognize the limited ability of consumers to distinguish among levels of scientific support, especially when the support is characterized using language that reflects fine nuances in the data, best appreciated by scientific experts. We would be please to discuss these comments upon request.

Respectfully submitted,

A handwritten signature in black ink that reads "John Ruff". The signature is written in a cursive, slightly slanted style.

John Ruff
Sr. Vice President
Worldwide Quality, Scientific Affairs & Compliance