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

Re: Docket No. 2003N-0496
Food Health Claims and Dietary Guidance
68 Fed. Reg. 66040 (November 25, 2003)

Nestlé USA markets food products in a wide variety of categories. We submit these comments in response to the advance notice of proposed rulemaking (ANPR) in which the Food and Drug Administration (FDA) requested comments on several issues surrounding the question of how the labeling of conventional food products and dietary supplements might best be used to deliver messages about health and dietary guidance, including qualified health claims.

Because of its global commitment to nutrition research, Nestlé has long been interested in the evolving regulatory environment for health-related messages on food products. Thus, even though we participated in and generally agree with the comments made by both GMA and NFPA, we hope to be able to provide the additional focus and perspective of an individual company. We welcome the increasing opportunities being provided by FDA to communicate with our consumers about how food choices may contribute to their health. We take very seriously our commitment to ensuring that our communications do not mislead consumers in any way. And, we believe that, in order for consumers to truly take responsibility for choosing a diet that may improve their health, they will need not only more and better information on the links between nutrition and health, but also a better understanding of the scientific process by which these links are established.

A Workable Regulatory Mechanism

Nestlé recognizes the difficulty of the task before FDA. On the one hand is the need to develop and implement a legally defensible mechanism for communicating to consumers early on about the role a given dietary substance may play in reducing the risk of disease, even though the scientific support for that role is less than definitive. On the other hand is the need to ensure that the mechanism is sufficiently clear and specific to permit prompt enforcement action to discourage the dissemination of false or misleading information – information that could undermine the ultimate goal of enabling consumers to choose food wisely. To address both these needs, we believe that the preferred regulatory model for communicating emerging or "qualified" health claims is one that reflects the way science works. As a general rule, science is a gradual

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process of consensus building. It begins with interesting, suggestive findings and builds progressively upon a body of increasingly credible data. The disclosure of uncertainty along the way is a key part of this process. Paradoxically, disclosing uncertainty helps inform what is known and what needs to be known.

We recognize that permitting labeling claims in advance of scientific consensus on the validity of the relationship that is the subject of the claim is, to a large extent, new territory for FDA. With this territory comes the necessity of accepting some level of uncertainty in the validity of a given substance/disease relationship. As is the case with good science, clearly communicating that uncertainty is an essential part of being able to ensure that the relationship is understood, and the wording of any claim must reflect that uncertainty. In this context, however, clear claim wording cannot be crafted without first conducting an accurate assessment of the level of scientific certainty about the underlying substance/disease relationship, as described in the agency's Interim Guidance.

As noted in the ANPR, regulating qualified health claims under the NLEA health claims rubric, as described in Option 2, is destined to conflict with the 1st Amendment unless FDA changes its approach to apply the Significant Scientific Agreement (SSA) necessary for an NLEA health claim to the specific *wording* of the claim, rather than to the validity of underlying *relationship*. While such a change in approach is legally defensible, it would create an unwieldy procedure where each and every potential modification of the wording must be assessed by the agency's best scientific minds – and then *reassessed* as the body of science in support of the relationship continues to build. In addition, such an unwieldy and time-consuming procedure is in direct conflict with the effort to get potentially helpful information to the consumer as early as possible. The very nature of the message that requires qualification – that it is emerging, preliminary or inconclusive – indicates that it should be processed in a way that allows it to reach consumers looking for such information quickly, slowed only by the need to ensure that it is appropriately qualified.

On the whole, we believe that each of the regulatory options proposed by the agency offers a defensible alternative for attempting to meaningfully communicate the quality of scientific evidence in support of a substance/disease relationship. Yet, as NFPA and GMA have ably articulated, none of the alternatives is completely satisfactory as a practical, workable mechanism. That said, we believe that Option 1 provides the most reasonable framework within which to operate. We question, however, the wisdom of proceeding at this point in time with a rulemaking effort to codify Option 1. The agency's role in the process of regulating qualified health claims is at an early stage of evolution – and so, too, is our understanding of what information is and is not meaningful to consumers. Unlike rulemaking, a guidance document would provide FDA the flexibility needed to adapt to such evolution. Moreover, reliance on criteria and guidances not embodied in final rules is consistent with how FDA conducts its GRAS notifications and new plant variety consultations. Each of these systems has benefited from the ability to efficiently implement new understanding and experience and to accommodate change as needed.

By suggesting that Option 1 be implemented by a guidance document as opposed to rulemaking, we recognize that we are also suggesting that the qualified health claim review process, like the GRAS notification process, be a "voluntary" one. There are several reasons for our comfort with this recommendation. Among these is the question whether FDA can lawfully *require* the submission of qualified health claims. There is, however, no basis to question FDA's ability to evaluate and, as necessary, take action against claims that violate the Food, Drug, and Cosmetic Act and are not protected by the First Amendment. Moreover, and simply stated, systems like the GRAS notification process work. They encourage consultation with the agency. They reward consultation by providing a clear decision as to whether a claim is objectionable. And, they efficiently allocate agency resources.

In adopting a voluntary notification approach for qualified health claims, FDA would agree to review a proposed claim and a summary of the supporting evidence and then to provide either a "no questions" or a "notice does not provide a basis" response. In a case where the agency had "no questions", FDA also would agree not to object to a statement (on the label or elsewhere) to the effect that "FDA has been notified of this claim and has no objection to its use." Admittedly, some educational effort would have to be provided to ensure that consumers understand the significance of such a representation. But, the upshot would be a clear incentive to industry to participate in this voluntary notification process.

Strategic Incentives

Nestlé suggests that several kinds of incentives may be needed to make the overall regulatory mechanism for health claims – whether qualified or unqualified – work to the greatest advantage of the consuming public. As described above, a voluntary notification process will provide inherent incentives for participation, as long as that process gives participating companies confidence to proceed when their messages are well-founded, and leaves them with sufficient flexibility in wording to create messages that are attractive to consumers.

Of course, one important goal of any health claim throughout the continuum of scientific support should be to clearly convey the level of sound science that supports the relationship described. Whether most consumers will be interested in distinguishing all four levels of support described in the Interim Guidance remains to be seen; a simpler system identifying just two or three levels – e.g., preliminary, promising and proven (SSA) – may ultimately be more useful to them. But, it is certain that in order to motivate consumers to make food choices based on health messages – and at the same time motivate marketers to use such messages – the wording of allowable claims at each level of scientific support must also be as attractive as possible. FDA has protected the area of "disease" claims for so long that the agency may assume such claims are inherently powerful drivers of behavior change. Marketers, on the other hand, know that at least in the context of foods, consumers often prefer claims that focus on taste and convenience. It may take more to change consumers' food choices than a subtle mention, in cautious scientific terminology, of the possible impact of the food on their future health. And, until marketers believe that such claims can truly impact consumers' decision making, they will be reluctant to use them at all.

Additional incentives may be needed to motivate industry to sponsor ongoing research in support of ever-stronger health messages. Permitting appropriately qualified claims to be made before SSA is reached will help justify investment in the necessary early research. Moreover, permitting qualified health claims has the potential to make more meaningful for consumers, and more valuable to marketers, the stronger message communicated in an SSA health claim. While we have already described the importance of attractive claims at any level of scientific support, there should be a clear hierarchy of messages that are allowed to be made more attractive and compelling as the science in support of a given diet/disease relationship increases. Thus, we welcome FDA's suggestions in the ANPR for improving the language of the SSA health claims at the top of the message hierarchy. As we have seen with health claims over the last decade, if the allowable message is too long, too difficult to understand, too vague – or otherwise more like a warning statement than a marketing claim – then neither the incentive for consumers to act on such a message, nor the incentive for companies to do the research necessary to support such a message, will be very great.

Enhancements like removing the word "may" from an SSA health claim would not only increase the attractiveness of the message, it would also help convey the higher level of scientific consensus supporting an unqualified health claim as opposed to a qualified health claim. Allowing such phrases as "FDA authorized" or "FDA approved" may also be helpful in this regard, especially if the agency is willing to educate the public about the way in which this "authorization/approval" process works. In keeping with the hierarchy of messages, whatever phrase is used for SSA health claims would certainly have to reflect a higher level of authorization than that allowed in conjunction with a qualified health claim reviewed under the voluntary notification process. More work is also needed with regard to the length and lack of impact in the wording of currently authorized SSA claims. Wherever scientific details are truly necessary, creative ways should be allowed to highlight a shorter version of the message in a key part of the label, while referring the reader to the full claim on another part of the label.

Implementation Through Education

Nestlé believes there are several ways in which FDA can promote both the communication of helpful nutrition and health information and the ability of the consumer to select and use that information appropriately. We do not believe the agency's responsibility extends to teaching consumers basic nutritional science or suggesting changes they might make to improve their health, although FDA's regulatory mechanisms should motivate industry to help with that education process. FDA can help by first ensuring that its regulatory rubric reflects the way science works – gradually moving from interesting initial findings to building a body of increasingly credible data – and then clarifying, for both consumers and industry, how the web of different health-related claims allowed by the regulatory rubric work together to inform and protect consumers. Ultimately, FDA is in the best position to help teach consumers how science works by teaching them how the labeling rules work to reflect the scientific process. The agency's allies throughout HHS and NIH can be instrumental in this education process, as well.

Dietary Guidance claims are an area where clarification, in the form of more regulatory guidance, is definitely needed. As the agency has already pointed out, Dietary Guidance claims

are not subject to the NLEA health claims rubric because they lack either the "substance" or the "disease" component of the substance/disease relationship. FDA has already issued extensive guidance on what constitutes a "disease" reference for this purpose and what does not, in the form of a dietary supplement labeling regulation (21 CFR §101.93(f) and (g)). The agency has recently explained that a Dietary Guidance claim referring to a "category" of foods instead of a "substance" may characterize the relationship between that category and a "disease" without pre-market approval. But, further guidance is needed on where the line is to be drawn on the continuum between "category" and "substance". For example, even the category comprising fruits and vegetables is the subject of an approved NLEA health claim, and the category of nuts is the subject of a qualified health claim to which the agency has agreed not to object. Unless, food companies gain a better understanding of where the safe harbor lies in Dietary Guidance claims, these types of health messages are unlikely to be widely used.

An even more important educational focus for FDA is ensuring that consumers understand the regulatory system and the scientific process it reflects. As with NLEA nutrition labeling, an understanding of the regulatory regime surrounding health-related messages is essential to consumers' ability to rely on and use the important health and nutrition information provided. And, as with the excellent educational effort FDA conducted around the introduction of NLEA nutrition labeling, this educational effort should not be considered "optional". Not all consumers use health-related messages in the same way. Some are very interested in making changes based on emerging scientific insights; others want to wait until a gradually accumulating body of science renders a specific diet/disease link very unlikely to be overturned. FDA's educational efforts have the potential to empower and inform both types of consumers.

Of course, FDA is not alone in this enterprise. Industry must accept the goal of improving the consumer's ability to choose food wisely. Implicit in this acceptance is not only the fostering of sound science but also the observance of marketing restraint and the willingness to self-police. The potential benefits of a system that encourages the dissemination of valuable nutrition and health information demand nothing less than such a commitment by all parties involved.

Yours truly,

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