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Dockets Management Branch, FDA-305
5600 Fishers Lane, Room 1061
Food and Drug Administration
Rockville, MD 20852

RE: Docket No. 03N-0069, Consumer Health Information for Better Nutrition

The Council for Responsible Nutrition (CRN) appreciates the opportunity to comment on FDA's initiative on Consumer Health Information for Better Nutrition. CRN shares the agency's commitment to providing consumers with information about the role of sound dietary practices -- including responsible use of dietary supplements -- in achieving and maintaining good health. In order for this information to have maximum benefit to consumers, it is critical that there be a high level of public confidence that the information provided is truthful, non-misleading, and based on sufficient scientific evidence. A large body of scientific evidence indicates that improved dietary habits can help reduce the risk of certain diseases and thereby improve the public health and potentially reduce health care costs.

The Council for Responsible Nutrition is one of the industry's leading trade associations. CRN represents a wide range of manufacturers of dietary supplement ingredients and of finished products, including national brands and store brands available in the mass market and products distributed through natural food channels, as well as dietary supplements marketed through direct sales and by mail order.

FDA has requested input from stakeholders on six key questions relating to health claims, including qualified health claims, evaluated by FDA under the provisions of the Nutrition Labeling and Education Act (NLEA). CRN participated in a recent stakeholders meeting with FDA officials on this topic, and below we provide our written comments on four of these questions. We have also submitted, separately, a joint comment with the Consumer Healthcare Products Association relating to the equal treatment of dietary supplements and conventional foods with regard to structure/function claims based on nutritive value.

What body of scientific evidence should be adequate for a qualified health claim?

The courts have made it clear that there are First Amendment issues raised when FDA prohibits health claims that are not false and misleading but that fail to meet the NLEA standard of being supported by significant scientific agreement. As a result, the courts have required FDA to consider, before denying a health claim outright, whether there is an appropriate disclaimer that could be added to the claim or alternative qualifying language for the claim that would accurately inform consumers about the nature and degree of the evidence supporting the statement. In response, FDA has recently permitted several qualified health claims to be utilized.

CRN believes it is important that qualified health claims be supported by credible evidence, and that the disclaimer not be used as an excuse for permitting claims that are not well supported. The Federal Trade Commission's application of its standard of "adequate and reliable scientific evidence" may provide the most relevant example of an appropriate standard that permits a wide variety of statements to be made while still requiring a solid basis for the claims. The FTC approach also has the virtue of being somewhat flexible, depending on the exact language of the claim being made. That is, a claim is required to have the level of support claimed or implied by the statement being made.

In considering NLEA health claims, CRN believes FDA would serve itself and consumers well if the agency adopted the view that it is the claim itself and not the underlying nutrient/disease relationship that must the subject of significant scientific agreement. Consistent application of this approach would essentially encompass qualified health claims and perhaps avoid the need for a separate approach to qualified claims.

CRN is concerned about the "good news, bad news" format FDA has adopted for expressing qualified claims. These claims start out with an affirmative, unqualified statement and then essentially say that FDA does not believe it. This construction seems unlikely to provide consumers with a good understanding of the nature of the support that exists for the statement or the reasons for FDA's unfavorable view of the claim. We urge the agency to consider a more unified and informative statement as an alternative.

Following is the text of the qualified claim relating to B vitamins, homocysteine lowering, and risk of vascular disease. This language follows the "good news, bad news" format mentioned above, which we believe may be confusing to consumers.

> As part of a well-balanced diet that is low in saturated fat and cholesterol, Folic Acid, Vitamin B6 and Vitamin B12 may reduce the risk of vascular disease.*
>
> *FDA evaluated the above claim and found that, while it is known that diets low in saturated fat and cholesterol reduce the risk of heart disease and other vascular diseases, the evidence in support of the above claim is inconclusive.

Consumer focus groups may be helpful in determining whether this informs or confuses consumers regarding the validity of the claim or the degree of evidence supporting it. CRN suggests that it may be more helpful to spell out the situation more clearly, possibly with language such as that adopted in the qualified claim for selenium. This language is offered as a general comparison, although we do not agree in all respects with the terminology. Specifically, we do not agree that the existing evidence on selenium and certain cancers is "limited."

> Selenium may reduce the risk of certain cancers. Some scientific evidence suggests that consumption of selenium may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive.

FDA tentatively plans to approach qualified health claims by requiring that a petitioner begin by submitting a request for an unqualified claim. Only if FDA concludes that an unqualified claim cannot be approved will the agency move on to considering a qualified claim. CRN joins other food industry associations in urging FDA to avoid unnecessary duplication of effort both for industry proponents and for the agency by permitting the direct submission of a petition for a qualified health claim.

What types of safety concerns should be factored into FDA decision-making?

CRN believes the agency's current policy of requiring that the food substance that is the subject of a health claim be "lawful" is sound. This has already been interpreted with some flexibility, allowing FDA to conclude that a substance is suitable for a health claim at the time the petition is evaluated. Clearly it is important for the agency and the industry to work together to ensure themselves as well as the public that consumers can safely increase consumption of the substance that is the subject of the health claim.

What specific claims may currently be ready for consideration under the new guidance?

CRN has not prepared a list of claims that companies may currently be considering. However, a review of some recent reports suggests several possible qualified claims that may be of interest. For example, B vitamins may play a role in protecting cognitive function and reducing the risk of dementia. Vitamin D certainly plays a role, along with calcium, in reducing the risk of osteoporosis, and there is also evidence supporting a role for vitamin K. Chromium may aid in controlling blood glucose levels in the general population or specifically in persons with diabetes. Antioxidants including vitamin C may delay onset of cataracts, and carotenoids such as lutein may reduce the risk of macular degeneration. Magnesium may play a role in protecting against hypertension and cardiovascular disease.

Going beyond the area of vitamins and minerals, there are some dietary supplements that currently bear structure/function statements but that may be eligible for qualified health claims relating to specific disease conditions. For example, glucosamine and chondroitin

sulfate may help reduce the risk of arthritis, and ginger may protect against motion sickness. We recognize that in both of these cases, the eligibility of the substance under the general requirements for health claims must also be considered.

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

Dietary supplements are a subcategory of foods, and have been so for as long as they have been marketed. The 1938 Food, Drug and Cosmetic Act created a category of foods for special dietary use, and the definition adopted by FDA in 1941 included supplementing the diet among the special dietary uses of foods. For many decades thereafter, labeling requirements for added nutrients were the same for fortified foods and nutritional supplements. Amendments to the Act relating to vitamins and minerals in 1976 and to dietary supplements in 1994 reaffirmed that supplements are to be regulated as a category of foods.

When NLEA was passed in 1990, it provided that there could be distinct systems established for regulating health claims for conventional foods and dietary supplements, but FDA concluded that the same standard and procedure should apply to both. Therefore, under the existing regulatory system, it is appropriate that dietary supplements and conventional foods should be treated the same for purposes of qualified claims as well as regular health claims, to the extent that they have the same capability for delivering a given benefit. FDA has taken this approach in its evaluation of NLEA health claims up to now, as is appropriate.

When a health claim relates to the increased consumption of a particular nutrient or other food substance and when the substance can be provided either by a conventional food or a supplement, both should be eligible for the claim. FDA has already taken this approach with regard to health claims for calcium in reducing the risk of osteoporosis, for example, as well as in several other health claims and qualified claims.

CRN sees no rationale for excluding conventional foods from eligibility for qualified health claims, and we applaud the new Commissioner's decision to extend eligibility for qualified health claims to conventional foods.

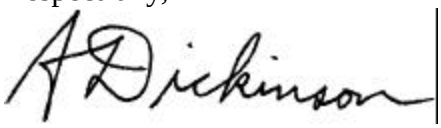
While equal treatment should guide FDA's actions in considering health claims and qualified claims, that is not to say there may not be some instances in which a claim will not apply equally to all products or to all categories of products. For example, FDA authorized a general health claim for foods naturally high in soluble fiber related to reducing the risk of heart disease, based primarily on epidemiological evidence relating to high-fiber diets and not related to evidence for the effect of any particular fiber source. This claim may have been appropriately limited to conventional foods. On the other hand, the claims FDA has approved for specific soluble fibers have been made available both to supplemental forms of the fiber and to conventional foods containing the fiber, provided the products meet the minimum requirements for the amount of fiber required per serving.

There may well be other instances in which some health claims and qualified claims should not be available to all products or all forms of a nutrient. CRN believes this should have been the case with respect to the folic acid health claim. Virtually all of the evidence on folic acid and neural tube defects is based on the benefits of supplemental folic acid. This claim could have been and probably should have been limited to dietary supplements and fortified foods providing 400 mcg of folic acid per serving and should not have been made available for conventional foods providing only a small fraction of this amount, in a less bioavailable form.

Conclusion

CRN supports FDA's initiative to provide consumers with more health information for better nutrition, and we appreciate this opportunity to provide comments on some of the aspects of this initiative being considered by a special Task Force.

Respectfully,



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