

FDA Public Meeting on “Functional Foods,” Dec. 5, 2006

Comments from the Council for Responsible Nutrition*

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The Council for Responsible Nutrition (CRN) is pleased to be able to offer its views at today's public hearing on products being marketed as "functional foods." CRN represents both manufacturers and ingredient suppliers that provide raw ingredients to both the dietary supplement and "functional food" industries. While the stated purpose of today's hearing is to seek comment "on approaches to the regulation of conventional foods being marketed as 'functional foods'," CRN wishes to emphasize that the policy directions promoted today will undoubtedly impact both conventional foods and dietary supplements.

Given that reality, CRN's request is that all stakeholders involved in this debate "proceed with care" and display a full appreciation for the interrelationship between these categories. A key unspoken question for this meeting is to what degree should dietary supplements and "functional foods" be regulated in a consistent manner?

But asking this question does not presume that functional foods and dietary supplements should be regulated identically. Several facts illustrate the relevance and importance of this question:

- The first is the increased prevalence of conventional foods being labeled and represented as dietary supplements (with the "Supplement Facts" box and disclaimer language mandated by DSHEA for supplements that make structure/function claims).
- At the same time, dietary ingredients commonly found in dietary supplements are also appearing with more frequency in conventional food forms that are labeled as foods, using the "Nutrition Facts" box.
- For all practical purposes certain aspects of the intended use of dietary supplements and functional foods have become strikingly similar (A proposed definition for "functional foods" reads as follows: "...foods or food components that provide a health benefit beyond basic nutrition").

FDA will need to fully understand and appreciate the consumer-driven marketplace as well as the regulatory imbalances that exist between these two categories that are driving the blending of these product lines.

Despite the similarities, many differences currently exist between the two categories, both in terms of how they are consumed and how they are regulated. For example:

- Different safety standards (i.e., reasonable certainty of no harm for food additives vs. reasonable expectation of safety for dietary supplements)
- Different manufacturing standards (e.g., food GMPs vs. proposed GMPs for dietary supplements).
- Differences in allowable claims (DSHEA expressly authorized the use of structure function claims for supplements but not foods).
- Differences in labeling (disclosure of amounts of all added functional ingredients for supplements, but not foods; FDA disclaimer statement for supplements but not foods)
- Functional foods may taste good and provide either thirst quenching or satiety, and thus may be consumed casually primarily for these purposes.

Any action taken by FDA, including no action has the potential for significant ramifications:

- If the Agency attempts to “streamline” the regulations between dietary supplements and functional foods, they face several imposing obstacles, the most daunting of which may be the chosen standard for safety.
- If the Agency proceeds with the recommendation to implement the generally recognized as efficacious (GRAE) concept being proposed or entertains the notion of providing incentives to companies to research their “functional food” products, surely the same would need to be considered for dietary supplements.
- If the Agency decides that the current regulatory framework for “functional foods” is sufficient (i.e. as conventional foods), and chooses to take no action, this decision could also be met with consequences. The disparities that currently exist between dietary supplements and “functional foods” may become more prevalent as the market expands, perhaps leading to more confusion (related to labeling, manufacturing, representing conventional foods as dietary supplements).

Therefore, it is the recommendation of CRN that FDA consider and review carefully all of the issues and all ramifications of any decision on both conventional foods and dietary supplements before proceeding with any action.

In the end, FDA’s most important concern should be assuring consumers that they receive safe products and sufficient truthful information to make informed purchase and usage decisions – regardless of which category the product is regulated under. Both consumers and industry will be well-served if the outcomes of today’s hearing lead to a further commitment to safety, more accurate and understandable information in the hands of consumers and more innovation and research in the product development process.

* The Council for Responsible Nutrition is the leading trade association representing dietary supplement manufacturers and ingredient suppliers. CRN companies produce a large portion of the dietary supplements marketed in the United States and globally. CRN's member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug store and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. CRN's 70+ manufacturer and supplier members agree to adhere to voluntary guidelines for manufacturing, labeling and marketing and CRN's Code of Ethics.