

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

Comments from the Council for Responsible Nutrition*

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Proceed with caution!

The Council for Responsible Nutrition’s (CRN) advice to *ALL* stakeholders involved in this debate is “proceed with caution”. A key underlying question which FDA appears to have avoided but which is clearly evident is, “Should dietary supplements and “functional foods” be regulated in a consistent manner?”.

Several facts illustrate the relevance and importance of this question:

- The increased prevalence of beverages (conventional foods) being labeled and represented as dietary supplements
- Questions posed by FDA in preparation for this meeting, eluding to topics such as pre-market notification, allowance of structure-function claims and whether the current safety standard (i.e. reasonable certainty of no harm) is appropriate for “functional foods”
- And the obvious fact that for all practical purposes the intended use of dietary supplements and functional foods has become strikingly similar

Despite the similarities, many disparities currently exist between the two categories:

- Different safety standards (reasonable certainty of no harm vs. reasonable expectation of safety)
- Different manufacturing standards (i.e. food GMPs vs. dietary supplement GMPs)
- Differences in allowable claims (DSHEA and 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 often taste good and provide either thirst quenching or satiety, and thus are often consumed casually, with perhaps less regard for the need to limit their intake

Any action taken by FDA, including no action has the potential for drastic ramifications. In attempting to “streamline” the regulations between dietary supplements and functional foods, the Agency faces several imposing obstacles, the most daunting of which is the chosen standard for safety. If the Agency proceeds with the recommendations of some and implements the generally recognized as efficacious (GRAE) concept 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 will also be met with consequences. The disparities that currently exist between dietary supplements and “functional foods” will only become more prevalent as the market expands, leading to more confusion (related to labeling, manufacturing, representing 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 before proceeding with any action.