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Conventional Foods Being Marketed as “Functional Foods”

Official Comments from the Association of Food and Drug Officials (AFDO)

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The Association of Food and Drug Officials (AFDO) is a non-profit professional organization consisting of state, Federal, and local regulatory officials as members, with industry representatives participating as associate members. From its very inception over 110 years ago, AFDO has recognized the need for uniform laws and regulations and has actively promoted uniformity and cooperation among regulatory agencies at all levels. AFDO strongly supports FDA's desire to develop effective strategies for the proper regulation and labeling of conventional foods that are marketed as functional foods.

While AFDO believes that existing laws and regulations governing the safety and labeling of food products are broad and comprehensive, we do believe a separate and distinct category for functional foods may be necessary. The definition of functional foods should also be clearly defined. Under FDA's current regulatory structure, conventional foods are permitted to make nutritional claims that are approved and can be found in the Code of Federal Regulations (CFR). These conventional foods may also make structure function claims under the Dietary Supplement Health and Education Act (DSHEA) just as dietary supplements can do. If, for instance, a conventional food has been shown to “maintain normal blood cholesterol levels”, then such a statement can be indicated on its label. It does appear, at first glance, that current laws and regulations already cover food and ingredients relative to safety and benefit claim. Food companies, however, are engineering more and more foods these days to have an effect on some structure or function of the body. Although AFDO would have no problem with a separate category for functional foods, we would be averse to doing away with the requirement that ingredients in conventional foods must be generally recognized as safe (GRAS) or shown (to FDA and to the States) that they are safe according to the Food Additive Amendment (FAA) as it is being used in the food. Consequently, other than calling a food a “functional food,” we could not go along with permitting the manufacturers of these types of food the same latitude that DSHEA gives to dietary supplements.

Additional comments for consideration as follows:

1) AFDO will continue to support the current regulatory framework for conventional foods, but will leave the door open to suggestions for a new classification of “functional foods” as long as the safety of these foods and the ingredients they contain is in no way compromised.

- 2) AFDO can further support industry proposing new or different claims (similar to approved nutrient content claims) for FDA to consider, as long as the amount and quality of the data needed to support such (claims) is not compromised. Right now there appears to be much hype associated with such “conventional” foods as energy drinks and bars.
- 3) AFDO believes that food companies wishing to market foods as “functional foods” should provide advance notification to FDA of the safety of the food ingredients (GRAS), and provide evidence to substantiate products provide the health benefits they claim.
- 4) Food companies should provide advance pre-market information to FDA about structure-function labeling claims, and provide evidence that the food or ingredients do provide a structure-function benefit.
- 5) Regulation or guidance should be developed by FDA and provided to food companies to be used in the framework for evidence needed for FDA support of structure-function claims.

AFDO is pleased to offer these comments to FDA as they consider this important issue. As our elderly population grows and we continue to become more health conscious, we must make sure that all foods promoting better health and longevity of life are marketed and labeled honestly for the consuming public. Clearly, this matter will continue to grow.

Respectfully,



Charlene Bruce, President
Association of Food and Drug Officials