

FDA PUBLIC MEETING ON FUNCTIONAL FOODS

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STATEMENT OF ANNETTE DICKINSON, Ph.D.

I appear on my own behalf, as a nutrition and regulatory affairs professional with a long history of interest in issues relating to the formulation and labeling of foods and dietary supplements marketed on the basis of health benefits. I am currently a consultant on scientific and regulatory issues affecting dietary supplements.

As a result of DSHEA, dietary supplements, although they continue to be classified and regulated as a category of foods, are subject to some unique requirements pertaining to ingredient safety, nutrition labeling, and structure/function claims. To the extent that dietary supplement requirements differ from those applicable to conventional foods, it is natural that questions would arise about the desirability of bringing the requirements closer together. These questions are of concern to the dietary supplement industry as well as the conventional food industry, which explains why both segments are represented at this meeting. Any changes in regulatory policy that may eventually be proposed by FDA should not only protect the consumer but also treat the various food industry segments fairly, without favoring one over the other.

NUTRITION LABELING

I would like to address an important issue that was not raised in the notice of this meeting, but which I believe is critical to consumers attempting to choose among the various dietary supplements and functional foods that are marketed on the basis of the health benefits they provide. Consumers need to be provided with full information about the identity and quantity of functional ingredients in such products, in order to permit meaningful comparison among products. I therefore urge FDA to require functional foods to include information on the identity and quantity of functional ingredients or components in the Nutrition Facts box or in an extension below the box.

Nutrition labeling for dietary supplements requires the Supplement Facts box to list the quantitative amount per serving of every dietary supplement ingredient in the product, with a partial exception for proprietary blends. In contrast, nutrition labeling for conventional foods requires statement of quantitative amounts per serving only for macronutrients. Vitamins and minerals appear only as a percent of the daily value, and other functional ingredients are excluded by regulation from the Nutrition Facts box, although they may be mentioned and quantified elsewhere on the label.

It would better serve consumers if the name and quantity of any food ingredient that is the subject of a functional claim were listed in the Nutrition Facts box -- or in an extension of the box that appears below it, a practice now being adopted voluntarily by some companies. This would allow consumers to compare various functional foods as well as dietary supplements in terms of the amount of a specific ingredient or component it contains, and FDA has the authority to require such labeling.

NLEA specifies the nutrients to be included in nutrition labeling for conventional foods, but also gives FDA the authority to expand the list of nutrients or other components to be included. FDA should exercise this authority to require fully informative labeling for foods making functional claims. A couple of examples will illustrate the problem faced by consumers in the current marketplace.

Energy beverages have become enormously popular, and consumers are using them without full awareness of the identity and quantity of their functional ingredients. Red Bull, for example, has a very limited Nutrition Facts panel, as specified in current regulations, that does not provide quantitative information on the amount of taurine, caffeine, inositol, or glucuronolactone in the product, although these do appear in the ingredient list. More informative labels are provided by Arizona Tea and by Glaceau, Vitamin Water on their energy formulas, which also bear the Nutrition Facts panel but provide additional information in an extension that appears below the usual facts box. The extension is headed "Performance Blend" in one case and "Also Contains" in the other, and lists the names and quantities of functional ingredients not permitted by regulation within the Nutrition Facts box. This additional information is important to consumers and should be required, not prohibited as is done under current nutrition labeling regulations.

A second example relates to foods containing omega-3 fatty acids. One brand of eggs currently on the market highlights the fact that each egg contains 225 mg of omega-3 fatty acids, and one brand of canned red sockeye salmon highlights the fact that each serving provides over 700 mg of omega-3 fatty acids. Neither label provides this information in the Nutrition Facts box, and neither specifies which omega-3 fatty acids it contains. Consumers may conclude that the two products provide similar benefits, but in fact the eggs contain only ALA, while the salmon provides EPA and DHA, which are more strongly related to health benefits for the heart. More specific information should be provided regarding the omega-3 fatty acids in these products, and the logical place for that information is in the Nutrition Facts box.

NOTIFICATION AND DISCLAIMER

DSHEA requires notification of FDA within 30 days of making a structure/function claim for a dietary supplement and also requires use of a disclaimer on the product label. Some now propose requiring the same notification and disclaimer for conventional foods making functional claims, but there is no apparent legal basis for extending these requirements to conventional foods.

SAFETY OF INGREDIENTS

FDA's primary concern, for both supplements and conventional foods, must be to ensure the safety of the ingredients and products offered to consumers. The GRAS process currently in place for conventional food ingredients is based on a rule that FDA proposed in 1997 but never finalized. It appears to be working well for all stakeholders, and there is no apparent reason why it is not as appropriate for functional food ingredients as for any other food ingredients. Indeed, many of the ingredients that have been listed since 1997 are functional ingredients. To the extent that stakeholders or FDA may wish to improve this system, those improvements could be made readily through guidance documents or in the final rule, since the current system is entirely a creation of FDA and not a system specified by law.

FDA's *laissez-faire* approach to notifications for new dietary ingredients of dietary supplements, by contrast, is not working well at all. The agency initiated a

discussion about improving this process in November 2004, but that discussion has not resulted in the issuance of guidance documents. Responsible companies wishing to introduce new ingredients have no map to follow, the rejection rate for notifications is high, and guidance is badly needed.

EXPERT PANEL DETERMINATIONS OF BENEFIT

IFT has proposed that FDA endorse the establishment of a system under which the benefits of functional foods could be established through review by an expert panel. This is similar to the current GRAS determination system, which also generally features the involvement of an expert panel. Whether or not FDA endorses this approach by regulation, it is an excellent concept which could be implemented voluntarily by marketers and which could bolster confidence in functional claims, both for conventional foods and for dietary supplements.

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