

# FDA's Crackdown on Cholesterol Structure/Function Claims: A Portent of Policies to Come?

by Jeffrey N. Wasserstein

This article examines the evolution of FDA's ever-narrowing policy regarding structure/function claims for cholesterol, and speculates on whether this narrow interpretation of acceptable structure/function claims, in conjunction with its approval of a cholesterol-related health claim, represents a new paradigm for FDA regulation of other structure/function claims.

## Background DSHEA and Structure/Function Claims

DSHEA permitted dietary supplement manufacturers to make claims characterizing the effect of a nutrient or dietary ingredient on the structure or function of the human body (structure/function claims) for their products so long as the manufacturer possessed data substantiating that the claims were truthful and not misleading, and the claim was accompanied by the "DSHEA disclaimer."<sup>1</sup> The manufacturer must notify FDA of the structure/function claim within 30 days of the initial marketing of the dietary supplement bearing the structure/function claim. Unlike drug and health claims, FDA does not have the authority to conduct a premarket review of the data substantiating a structure/function claim.

## FDA's Initial Policy—Plant Sterol/Stanol Ester Claims

FDA's best statement of its initial policy regarding cholesterol structure/function claims arose in the context of a

conventional food structure/function claim, not a dietary supplement. In April and May 1999, FDA approved the use of plant stanol esters and plant sterol esters in margarine-type spreads. These spreads were marketed as Benecol and Take Control by McNeil Consumer Products and Lipton respectively. Take Control was marketed for use in "maintain[ing] healthy cholesterol levels as part of a diet low in saturated fat and cholesterol" while the ingredients in Benecol were "intended for use as nutrients in food to reduce the absorption of cholesterol from the gastrointestinal tract." FDA, in letters to Lipton and McNeil regarding their submissions, noted that the proposed claims, "Helps promote healthy cholesterol levels as part of a diet low in saturated fat and cholesterol" (Take Control) and "Helps promote healthy cholesterol levels" (Benecol) were "within the purview of structure/function claims." FDA's initial stab at formulating a cholesterol structure/function policy was quite permissive, allowing claims to be made that ingestion of the product actually promoted healthy levels of cholesterol. These letters were relied upon heavily by the dietary supplement industry

*The Dietary Supplement Health and Education Act of 1994 (DSHEA) was intended to liberalize the Food and Drug Administration's (FDA's) policies regarding claims made for dietary supplements. DSHEA explicitly authorized claims characterizing the effect of a nutrient or dietary ingredient on the structure or function of the human body—the "structure/function claim" in common parlance.*



*Mr. Wasserstein is an Associate in the law firm of Hyman, Phelps & McNamara, PC, Washington, D.C.*

in formulating claims for cholesterol-related products.

## Narrowing the Claim—FDA’s Structure/Function Regulation

In January 2000, FDA promulgated its regulations on structure/function claims. 65 Fed. Reg. 999 (Jan. 6, 2000). As part of its lengthy preamble, FDA addressed structure/function claims for cholesterol. In response to numerous comments arguing that dietary supplement products should be allowed to make cholesterol-lowering claims, FDA drew a sharp distinction between cholesterol structure/function claims and implied disease claims regarding cholesterol. An appropriate cholesterol structure/function claim, according to FDA, refers to the maintenance of cholesterol levels already within the normal range, while a claim that a product lowers cholesterol is an impermissible implied disease claim. Having

## Plant Sterol/Stanol Esters Revisited

Recently, FDA further undercut its initial policy when it approved a health claim linking plant sterol/stanol esters and a reduction in the risk of coronary heart disease (CHD). 65 Fed. Reg. 54,686 (Sept. 8, 2000). Unlike structure/function claims, health claims may make explicit claims regarding the link between a particular nutrient or dietary ingredient and the reduction in the risk of disease. Products such as Benecol and Take Control, the very products for which FDA originally allowed the broader structure/function claim, can now claim that they might help lower the risk of CHD, which is a considerably stronger claim than even the original cholesterol structure/function claim. The products could also explain that the reduction in risk of CHD is through the intermediate link of “blood cholesterol” or “blood cholesterol and LDL cholesterol.”

*“The only cholesterol claim now permitted under the structure/function regulation implies that the product is not appropriate for consumers whose cholesterol is not already within normal limits.”*

by declaring that structure/function claims could not use the term “healthy cholesterol levels,” since “healthy cholesterol” is used frequently to refer to high density lipoproteins (HDL) and might therefore be misleading to consumers. To avoid this confusion, FDA then stated what it believed to be the appropriate cholesterol structure/function claim: “Helps to maintain cholesterol levels that are already within the normal range.”

This claim represents a significant narrowing of FDA’s policy regarding appropriate cholesterol structure/function claims. FDA’s policy shift in the structure/function regulations represents a sharp departure from the relatively permissive language of DSHEA. The only cholesterol claim now permitted under the structure/function regulation implies that the product is not appropriate for consumers whose cholesterol is not already within normal limits. This policy is without statutory support, and will result in cholesterol structure/function claims that are largely meaningless to consumers.

ester CHD heart claim, FDA began to issue numerous courtesy letters regarding structure/function claims for cholesterol. Some attacked the use of the term “healthy cholesterol” in accord with the structure/function regulation. Other courtesy letters attacked claims that would seemingly be permitted even under the agency’s narrow definition, including “retaining normal blood cholesterol levels,” “helps maintain normal cholesterol levels,” and “maintain normal cholesterol levels and blood pressure.” It would appear that unless a cholesterol structure/function claim parrots the exact language of the claim set forth in the preamble to the structure/function regulation, the promulgator of the claim may receive a courtesy letter. Again, FDA’s ever-narrower policy is inconsistent with DSHEA and is resulting in courtesy letters that attack claims that are well within FDA’s initial policy regarding cholesterol structure/function claims.

*Continued on page 45*

## Crackdown on Cholesterol

Continued from page 28

### Speculation: Where Is FDA Going With Its Structure/Function Policies

As is clear to anyone familiar with the dietary supplement industry, FDA does not like structure/function claims. This is likely due to the fact that, unlike drug claims and health claims, FDA cannot review the scientific data underlying the claims. What we have seen with cholesterol structure/function claims is that FDA narrowed its policy of appropriate structure/function claims almost to the point of insignificance, while at the same time approving an even stronger claim for products willing to submit to the more rigorous health claim scrutiny. By narrowing its definition of appropriate structure/function claims to insignificance, FDA can push companies with sufficient resources into funding studies and submitting a health claim petition, while disallowing other structure/function claims. By doing this, FDA regains some control over the claim-approval process control it lacks, for the most part, in evaluating structure/function claims.

It is possible that this trend will continue in the future with other structure/function claims as well. For example, FDA initially noted in the structure/function regulation that a statement that a product could be “use[d] as part of your diet to help maintain a healthy blood sugar level” would be an acceptable structure/function claim so long as the product did not link the claim to diabetes. Recently, however, FDA issued several courtesy letters backing away from this

position. One, in particular, explained that although the preamble to the final structure/function rule did seemingly permit the blood sugar level claim, FDA believed that “any claim that a product is intended to maintain normal blood glucose levels is an implied disease

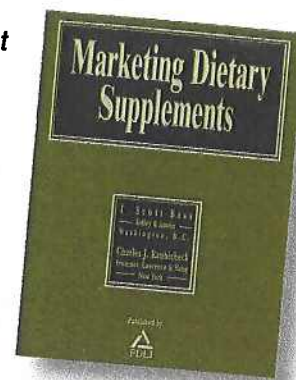
claim.” FDA stated that an appropriate claim for such a product would be that the product played a role in the “maintenance or regulation of blood glucose that is already normal or within normal limits.” As with the cholesterol claim, FDA is willing to permit only those claims where the structure or function at issue is already within normal levels.

### Conclusion

FDA may have seized upon a strategy designed to reassert control over dietary supplement structure/function claims. By permitting only insignificant structure/function claims and disallowing all others, FDA “encourages” supplement and food manufacturers with greater resources to seek a health claim, which allows FDA

**“This is the most lucid account of DSHEA and its implications for industry that I have read. Because it is so clearly and articulately written, it is also a great reference for others of us in the field of dietary supplements.”**

**Government scientist**



New from FDLI, *Marketing Dietary Supplements* is a concise, non-technical guide to marketing, establishing claims, and regulatory compliance for these complex and unique products. The advice offered provides keen insights into the realistic decisions you and your company must make in the current gray area surrounding claims, safety issues, and labeling in the United States, as well as the challenges you may face when marketing dietary supplement products overseas.

**\$179 Members • \$269 Non-Members**  
(2000/hard cover binder)

## Marketing Dietary Supplements

*I. Scott Bass and Charles J. Raubicheck*

To order call (800) 956-6293 or visit [www.fdl.org](http://www.fdl.org)



to review the data underlying the claim. Other claims besides cholesterol may also be susceptible to this strategy. Although there has not been a health claim petition filed for the blood glucose structure/function claim, FDA may be utilizing (perhaps subconsciously) a strategy similar to the one it successfully implemented with the cholesterol structure/function claim. This strategy bodes ill for the dietary supplement industry and is contrary to DSHEA. FDA’s course of action may ultimately be a matter for the courts to rectify. ▲

<sup>1</sup> “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.” 21 U.S.C. § 343(r)(6)(C).