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August 2, 2001

Via Federal Express

Hon. Tommy Thompson
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: United States Food and Drug Administration
Interim Final Rule Docket Nos. 00P-1275 and 00P-1276
"Food Labeling: Health Claims; Plant Sterol/Stanol Esters and Coronary Heart Disease" (65 Fed. Reg. 54686 (September 8, 2000))

Dear Secretary Thompson:

We are writing on behalf of Traco Labs, Inc. ("Traco"), the manufacturer of, among other things, Cholestatin®, a dietary supplement containing plant sterols/stanols, which has been clinically shown to contribute to reduced blood serum cholesterol. At the present time, because of the restrictive manner in which FDA has promulgated the above-referenced Interim Final Rule so as to authorize the use of a health claim only for plant sterol/stanol esters, Traco is prohibited from conveying this truthful, nonmisleading health information to consumers.

Following the failure of the Food and Drug Administration ("FDA") to fulfill its promise to issue a final regulation and respond to the clear evidence submitted to it by Traco and others demonstrating the need to amend the limited health claim created by the Interim Final Rule, and allow its use in association with an expanded range of foods and dietary supplements, Traco respectfully requests that you intervene and direct the agency to promptly respond to the comments submitted to it. In particular, Traco wishes to draw your attention to the fact that, by failing to act as promised, FDA has limited the use of the above-referenced health claim to fat-based products produced by major food and pharmaceutical companies, while prohibiting the dietary supplement industry from providing this important health information in association with its products. Traco further notes that FDA's inaction flies in the face of Third Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults ("ATP III"), by the National Heart Lung and Blood Institute, which recommends the inclusion of dietary plant sterols/stanols in a program of LDL cholesterol-lowering therapy.

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On September 8, 2000, the FDA issued the above-referenced Interim Final Rule authorizing the use of a health claim advising consumers of the association between the daily intake of foods that provide at least 3.4 grams of plant stanol esters taken during the course of two meals and/or 1.3 grams of plant sterol esters also taken during the course of two meals and a reduced risk of coronary heart disease. The Interim Final Rule, citing the specific health claim petitions submitted to FDA, however, restricted the use of these claims to two fat-based delivery systems: spreads and salad dressings. Indeed, the nature of these delivery systems necessitated the creation of special exceptions to the general rule prohibiting the use of heart disease health claims in association with fat-based foods.

In response to FDA's request for comments on the substance of the Interim Final Rule, on November 22, 2000, while applauding the agency's decision to recognize the importance of alerting the American public to an additional diet-related vehicle for reducing the risk of heart disease, Traco requested that FDA (a) expand the health claim to include free-form (non-esterified) plant sterols/stanols, and (b) permit the use of the health claim on properly qualified dietary supplement products. In support of this request, Traco submitted a proprietary, unpublished study conducted on its Cholestatin® dietary supplement, and provided FDA with a list of 17 published studies supporting the applicability of the health claim to free-form plant sterols/stanols. Significantly, five of the 17 published studies were cited by FDA in the *Federal Register* Notice accompanying the Interim Final Rule.[1]

By its own terms (and by statute), the Interim Final Rule was to have become final on June 5, 2001, subject to amendment by FDA. On June 6, 2001, having missed the June 5 deadline, FDA issued a *Federal Register* Notice extending the time by which it would respond to the comments it received to July 25, 2001 – at which time it was to have published at least a portion of a Final Rule.

To date, FDA has failed to publish any such Rule. July 25th has come and gone, and the only response from FDA has been a resounding silence. No official comment or notice to interested industry – and, more importantly, the consumer – has been forthcoming from the agency. This utter failure of action is inexcusable. At a time when FDA appears to have the resources to pursue a number of issues with little or no impact on the overall public health (for example, the inclusion of herbs in certain "beverages") and to continually litigate and re-litigate First Amendment issues relating to its complete lack of regard for orders of the United States District Court for the District of Columbia and the United States Court of Appeals in the Pearson

[1] A review of the FDA docket, as available on the Agency Web page, indicates that a number of other companies submitted comments substantially similar to those presented by Traco. To the extent that FDA received any negative comments, those appear to be related only to the Interim Final Rule's applicability sterol/stanol esters in fat-based delivery systems.

cases, FDA's failure to act here displays a shocking contempt for the health concerns of the American public.

Compounding matters, FDA has recently made it clear that it has little intention of devoting any substantial effort to addressing this important issue, as it has placed preparation of the Final Rule relating to plant sterol/stanol esters on the "B" list of priorities for the Center for Food Science and Applied Nutrition for 2001. In other words, the best anyone can hope for is a decision from FDA some time in 2002.

To the extent that the FDA believes that it has been presented with conflicting or unclear data relating to requests to reduce the daily dosage of plant sterol/stanol esters called for by the health claim, Traco respectfully submits that this is no excuse for its failure to at least amend the Interim Final Rule and allow the transmission of truthful and nonmisleading information relating to the association between foods and dietary supplements containing free-form plant sterols/stanols and the reduced risk of coronary heart disease. FDA's ongoing failure to act serves no public health purpose and only continues to deprive the American public of this vital information to which it is entitled.

At this juncture, Traco believes that it is imperative for your office to demand that FDA act upon the comments it has received, and, at a minimum, substantively address those seeking application of the health claim to free-form, non esterified, plant sterols/stanols, and expansion of the claim to other forms of food and dietary supplements. Without your intervention, Traco fears that FDA will continue to drag its feet on this important issue to the detriment of the overall health of the American public. Such negligence, which is reminiscent of the Agency's obstinate refusal to issue a health claim concerning the relationship between folic acid and neural tube defects, should not be deemed acceptable.

Respectfully submitted,

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cc: Hon. Tom Harkin, United States Senate (via Federal Express)
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