Council for Responsible Nutrition

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December 22, 2010

Dr. Barbara Schneeman,
Director
Office of Nutrition, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
United States Food & Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Re: Docket Nos. FDA–2000–P–0102, FDA–2000–P–0133, and FDA–2006–P–0033

Dear Dr. Schneeman:

In an email dated Monday, December 13, 2010 12:22 PM, I alerted you to a concern we have with a provision in FDA's proposed rule for Phytosterols and Risk of Coronary Heart Disease (CHD) published in the Federal Register on December 8, 2010.

> On page 76546 the FDA states:
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> "Beginning 75 days from the date the proposed rule publishes, FDA does not intend to exercise its enforcement discretion based on the letter issued in 2003…Until the agency issues a final rule amending the requirements of § 101.83, the agency believes that its exercise of enforcement with respect to claims that do not comply with current § 101.83 but do comply with the proposed rule is appropriate".

Our interpretation of this text is that FDA will cease exercising enforcement discretion with respect to the CHD health claim for dietary supplements containing free phytosterols 75 days after the publication of the proposed rule (i.e. 75 days after December 8, 2010), which means that enforcement discretion would end on February 22, 2011.

The intent of this letter is not to address FDA's position on whether dietary supplement products can bear the health claim, a matter which we intend to address separately in comments to the docket, but instead to urgently request an extension of the compliance period for the enforcement discretion policy that has been in effect since 2003.

The majority of phytosterol-containing dietary supplements currently bear the health claim (based on FDA's 2003 enforcement discretion letter), and nearly all include the free form of phytosterols, particularly solid tablet dosage forms. Therefore, dietary supplement companies may need to reformulate products and/or modify their labeling in order to be compliant with the proposed rule, but 75 days (now 61 days) is not nearly enough time for companies to implement these changes.

FDA-2006-P-0033 NET

Based on information provided by our member companies, CRN's conservative estimate is that at least 50 manufacturers and their products may be affected by this situation.

CRN requests that FDA temporarily continue to exercise its enforcement discretion and – in the event FDA does not ultimately decide to permit the CHD health claim for dietary supplements containing free phytosterols based upon submitted comments – allow an 18 month extension to provide manufacturers adequate time to make the necessary labeling, raw material, manufacturing and marketing changes.

An 18 month extension of the existing enforcement discretion policy would be consistent with FDA precedent,[1] and would also enable FDA to review substantive comments submitted to the agency during the 75-day comment period – rather than altering existing policy prior to engaging in such a review.

From a practical perspective, the following is a list of procedures supplement companies that manufacture and market free phytosterol-containing products would need to undertake in order to be in compliance with the proposed rule. These changes pertain to reformulating and relabeling products currently bearing the claim.

Reformulation

- Find and qualify a source of an esterified phytosterol raw material that would be suitable for a new product that would replace the existing free-form product
- Develop a new product formulation using esterified phytosterols
- Produce trial manufacturing batches of the new formula to support product development and adjust formula as necessary
- Conduct accelerated stability studies on trial batches of the new product to support expiration dating
- Order new raw materials and schedule the manufacture of the new product.
- Create and execute a marketing transition plan to introduce customers and consumers to the new product form
- Print new labeling materials (see above)
- Produce full-scale manufacturing batch to confirm final formulation.
- Package all remaining free-form bulk products in preparation for the transition to the new product

Relabeling

Whether or not products are reformulated, being in compliance with the proposed rule would require a label change.

- Initiate, review, and approve necessary change controls

[1] FDA traditionally provides food/supplement companies with at least two years to come into compliance with labeling policy changes pursuant to issuance of "uniform food labeling compliance dates," and FDA also grants drug companies at least one year, and often longer, to come into compliance with final regulations issued pursuant to the OTC Drug Review.

- Review and approve revised packaging artwork (by each responsible function)
- Update packaging specifications and bills of materials for each SKU
- Review and approve artist proofs
- Prepare and approve purchase orders
- Allow time for printer to manufacture the revised packaging components
- Review and release of new packaging components received at packaging site by Quality Unit
- Produce finished packaged product at packaging site and allow for Quality Unit to release
- Ship finished packaged product from packaging site to manufacturer and/or retailer distribution centers
- Ship finished packaged product from distribution centers to point of sale

According to our member companies, 18 months would provide appropriate time to complete the above procedures as well as cease manufacturing/packaging and exhaust inventory of the existing free phytosterol-containing products through retail. This will also allow time for an orderly transition of currently labeled to newly labeled products in the marketplace,a voids market disruptions and potential consumer confusion, and will include some reasonable cushion as a contingency for unexpected events. If the rule was limited to impacting only labeling changes, the requisite timeline needed would be shorter, but still significant (12 months) coupled with appropriate time to transition existing product inventories.

These lists of steps may not be all inclusive and the requested timeline may not reflect the needs of all free phytosterol-containing dietary supplement manufacturers. However, we feel that they adequately reflect what most firms would need to accomplish in order to be in compliance with the proposed rule.

Note also that there are significant costs associated with revising labels and reformulating a product which have not been highlighted in this letter. I would be happy to discuss these with you at your convenience.

We appreciate FDA's willingness to take this issue seriously and look forward to a prompt response.

Regards,

Andrew Shao, PhD
Senior Vice President
Scientific & Regulatory Affairs

cc: Blakeley Denkinger, Center for Food Safety and Applied Nutrition