FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR FOOD SAFETY & APPLIED NUTRITION

May 22, 2020

Anthony L. Young
Kleinfeld, Kaplan and Becker LLP
1850 M Street, NW, Suite 800
Washington, DC 20036

Re: Docket Numbers: FDA-2000-P-0102, FDA-2000-P-0133, FDA-2006-P-0033

Dear Mr. Young:

This letter is regarding the consolidated Petition for Stay of Action and Citizen Petition received by the Food and Drug Administration (FDA or we) on February 24, 2011, from your firm on behalf of Pharmavite, LLC ("Pharmavite").

The Petition for Stay requests FDA:

> "stay the February 18, 2011 decision to discontinue enforcement discretion as of February 21, 2012 for those dietary supplements containing free phytosterols that have been shown, through an adequate and well-controlled clinical trial, to reduce low-density lipoprotein cholesterol ('LDL-C') and total cholesterol, pending issuance of a final rule addressing the health claim for phytosterols and the risk of coronary heart disease ("CHD")."

The request for stay indicates that you are requesting that FDA continue to follow an enforcement discretion approach outlined in a 2003 letter (described below).

See Citizen Petition from Anthony L. Young and Jennifer A. Davidson, Kleinfeld, Kaplan and Becker, LLP, submitted to the Dockets Management Branch, Food and Drug Administration, dated February 24,2011, ("Petition") at page 3.

In addition, the Citizen Petition portion of your submission seeks:

- "FDA acknowledgement that, in light of clinical study information [enclosed with your petition], CholestOff® has been shown to effectively reduce LDL-C and total cholesterol," and
- "the Agency will continue to exercise enforcement discretion to permit CholestOff® to bear an appropriately worded claim [pursuant to the 2010 proposed regulation] describing the relationship between phytosterols and reduced risk of CHD, pending issuance of a final rule addressing the health claim for phytosterols and the risk of CHD," and

- "the final rule will allow those dietary supplements containing free phytosterols that have been shown through an adequate and well-controlled clinical trial to effectively reduce LDL-C and total cholesterol, such as CholestOff®, to bear the health claim."

(Petition at page 3.)

I. Petition for Stay

With respect to your Petition for Stay, we note that, since the receipt of your petition, we published a notice in the Federal Register of February 21, 2012 (77 FR 9842) ("the 2012 notice"), extending the period that we intend to exercise enforcement discretion until publication of a final rule. The notice followed a complicated regulatory history beginning on September 8, 2000, when FDA issued an interim final rule (IFR) (65 FR 54686) authorizing a health claim for plant sterol/stanol esters and CHD. Among other requirements, we established in the IFR that spreads and dressings for salads must contain at least 0.65 grams (g) of plant sterol esters per reference amount customarily consumed (RACC) to be eligible to bear the health claim and that spreads, dressings for salad, snack bars, and dietary supplements in soft gel form must contain at least 1.7 g of plant stanol esters per RACC to be eligible to bear the health claim. FDA received a letter, dated January 6, 2003, from Cargill Health and Food Technologies requesting that FDA issue a letter stating its intention not to enforce certain requirements in the IFR.

In response, FDA issued a letter of enforcement discretion explaining that FDA would consider exercising enforcement discretion, pending publication of the final rule, with respect to certain requirements of the health claim. Specifically, we stated that we would consider such discretion with regard to the use of the health claim in phytosterol-containing food, including foods other than those specified in 21 CFR 101.83(c)(2)(iii)(A), if: (1) the food or dietary supplement contains at least 400 milligrams (mg) per reference amount customarily consumed (RACC) of phytosterols; (2) mixtures of phytosterol substances (i.e., mixtures of sterols and stanols) contain at least 80 percent beta-sitosterol, campesterol, stigmasterol, sitostanol, and campestanol (combined weight); (3) the food meets the requirements of 21 CFR 101.83(c)(2)(iii)(B)-(D); (4) products containing phytosterols, including mixtures of sterols and stanols or free forms, use a collective term in lieu of the terms required by 21 CFR 101.83(c)(2)(i)(D) in the health claim to describe the substance (e.g., "plant sterols" or "phytosterol"); (5) the claim specifies that the daily dietary intake of phytosterols that may reduce the risk of CHD is 800 mg or more per day, expressed as the weight of free phytosterol; (6) vegetable oils for home use that exceed the total fat disqualifying level bear the health claim along with a disclosure statement that complies with 21 CFR 101.13(h); and (7) the use of the claim otherwise complies with 21 CFR 101.83. Thus, the 2003 letter described FDA's intended enforcement discretion with respect to: (1) different forms and mixtures of phytosterols in a wider variety of products; and (2) the use of the claim on foods containing lower levels of phytosterols than set forth in the IFR.

In the Federal Register of December 8, 2010 (75 FR 76526), we published a proposed rule that, if finalized, would amend § 101.83 (the 2010 proposed rule). The 2010 proposed rule also stated that, beginning 75 days after the date of publication of the proposed rule (February 21, 2011), FDA did not intend to exercise its enforcement discretion based on the 2003 letter (75 FR 76526 at 76546). We subsequently issued a notice in the Federal Register of February 18, 2011, extending the period during which we intended to exercise enforcement discretion based on the

2003 letter to February 21, 2012 (76 FR 9525). However, in the 2012 notice, we stated that FDA is extending the period during which it intends to exercise enforcement discretion, consistent with the factors set forth in the 2003 letter, until publication of a final rule for the phytosterols and risk of CHD health claim.

Given the publication of the 2012 notice extending our intention to exercise enforcement discretion until we publish a final rule, we conclude that the circumstances since the date you submitted your petition have rendered your petition moot. Accordingly, we are dismissing your Petition for Stay of Action in accordance with 21 CFR 10.35(e).

II. Citizen Petition

You request that FDA provide an "acknowledgement" that the CholestOff® product has been shown to effectively reduce LDL-C and total cholesterol. We do not generally make determinations about whether any particular product achieves its intended effects outside of the agency's formal product approval pathways, such as for new drug approvals. We do not have the resources or legal mandate to evaluate a products' purported effectiveness outside of the established pathways, and, as a matter of policy, we are concerned that any "acknowledgement" of a particular product's purported effectiveness would be viewed as endorsing particular products at the expense of others. Accordingly, we are denying this aspect of your citizen petition.

You also request that FDA continue to exercise enforcement discretion to permit CholestOff® to bear an appropriately worded claim pursuant to the 2010 proposed regulation describing the relationship between phytosterols and reduced risk of CHD, pending issuance of a final rule addressing the health claim for phytosterols and the risk of CHD. We stated in the 2010 proposed rule that if health claims are made in a manner consistent with the proposed rule, we would consider exercising enforcement discretion on a case-by-case basis pending publication of a final rule. FDA also stated in the February 18, 2011 notice and in the 2012 notice that we intended to maintain the same policy regarding how we intend to consider exercising our enforcement discretion when claims are made consistent with the proposed requirements in the proposed rule. Because FDA has reiterated its enforcement discretion policy since you submitted your petition, the circumstances since you submitted your petition have changed and we are dismissing this aspect of your petition as moot.

Finally, your citizen petition requests that the final rule allow those dietary supplements containing free phytosterols that have been shown through an adequate and well-controlled clinical trial to effectively reduce LDL-C and total cholesterol to bear the health claim. When FDA issues a proposed rule, such as the 2010 proposal, we note the comment period, which specifies how long the agency will accept public comments. We also provide instructions on how to submit comments. Because this aspect of your citizen petition request relates to an ongoing rulemaking and was not submitted in accordance with the comment procedures for the rulemaking, we are denying this aspect of your citizen petition.

III. Conclusion

In conclusion, we are dismissing your Petition for Stay as it is moot in accordance with 21 CFR 10.35(e) and we are denying and dismissing your Citizen Petition in accordance with 21 CFR 10.30(e)(2).

Sincerely,

Claudine Kavanaugh, Ph.D., M.P.H., R.D.
Director
Office of Nutrition
and Food Labeling
Center for Food Safety
and Applied Nutrition