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

May 22, 2020

Miriam J. Guggenheim
Covington & Burling LLP
One CityCenter
850 Tenth Street, NW
Washington, DC 20001-4956

Re: Docket Number: FDA-2000-P-0102

Dear Ms. Guggenheim:

This letter is regarding the Petition for Stay of Action received by the Food and Drug Administration (FDA or we) on January 7, 2011, from your firm on behalf of Cargill, Inc. (formerly Cargill Health and Food Technologies). The petition requests that FDA:

- "stay rescission of enforcement discretion under [FDA's February 14, 2003, letter of enforcement discretion to Cargill Health and Food Technologies] pending issuance of [a] final rule."

See Petition for Stay of Action from Gerald F. Masoudi, Eugene I. Lambert, Miriam J. Guggenheim, and Amalia L. Fenton, Covington & Burling LLP, submitted to the Dockets Management Branch, Food and Drug Administration, dated January 7,2011, at page 2.

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).

Sincerely,

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