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Sarah E. Taylor, J.D., R.D., M.P.H.
Covington & Burling
1201 Pennsylvania Avenue, N.W.
Washington, DC 20004-2401

RE: Health Claim Petition – Walnuts and Coronary Heart Disease
(Docket No. 02P-0292)

Dear Ms. Taylor:

This letter is to notify you of our decision with regard to the health claim petition submitted on March 15, 2002, on behalf of the California Walnut Commission. This petition requests that the Food and Drug Administration (FDA) authorize a health claim about the relationship between the consumption of walnuts and reduced risk of coronary heart disease (CHD) on the label or in the labeling of whole or chopped walnuts. Specifically, you request that FDA authorize the following model claim: "Diets including walnuts can reduce the risk of heart disease."

FDA filed the petition for comprehensive review on June 21, 2002, in accordance with section 403(r)(4)(A)(i) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 343(r)(4)(A)(i)). The initial deadline for FDA's response was September 19, 2002. After mutual agreement, the deadline for the agency's response was extended to subsequent dates, including December 18, 2002, February 28, 2003, June 16, 2003, and finally to July 14, 2003.

Based on our review of the scientific evidence, we conclude that there is not significant scientific agreement that consumption of walnuts may reduce the risk of CHD. Consequently, we cannot authorize a health claim by regulation pursuant to section 403(r)(3)(B) of the Act (21 U.S.C. § 343 (r)(3)(B)(i)) and 21 C.F.R § 101.14(c). However, we conclude that there is a sufficient basis for a qualified health claim about walnuts and reduced risk of heart disease.

FDA has decided to consider the exercise of its enforcement discretion with regard to the following qualified health claim with the disclosure statement on the label or in the labeling of whole or chopped walnuts as presented below:

- (1) "Supportive but not conclusive research shows that eating 1.5 ounces per day of walnuts as part of a diet low in saturated fat and cholesterol may reduce the risk of heart disease. See nutrition information for fat content."

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Walnuts are not unique among nuts in their effect on reducing the risk of heart disease. FDA believes that there is benefit in helping consumers understand the larger context that other nuts in addition to walnuts may have an effect on reducing the risk of heart disease. Consequently, FDA has also decided to consider exercising enforcement discretion with regard to the following qualified health claim which provides this larger context:

- (2) "Scientific evidence suggests but does not prove that eating 1.5 ounces per day of most nuts, such as walnuts, as part of a diet low in saturated fat and cholesterol may reduce the risk of heart disease. See nutrition information for fat content."

The disclosure statement referencing the fat content of food is to be placed immediately adjacent to and directly beneath the claim, with no intervening material, in the same size, typeface, and contrast as the claim itself (21 C.F.R. §§ 101.14(e)(3) and 101.13(h)).

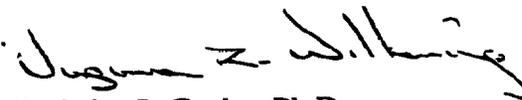
Whole or chopped walnuts bearing either of the above qualified health claims and applicable disclosure statement are still required to meet all applicable statutory and regulatory requirements under the Federal Food, Drug, and Cosmetic Act. However, there are certain exceptions to the requirements for health claims that the agency would consider as part of its enforcement discretion. Such exceptions would include compliance with the requirement that a health claim meet the significant scientific agreement standard and the requirement that the claim be made in accordance with an authorizing regulation. In addition, although walnuts exceed the total fat disqualifying levels for health claims in 21 C.F.R. §101.14 (a)(4), FDA believes that an appropriately qualified claim about consumption of walnuts would assist consumers in maintaining healthy dietary practices, provided that the label bears a disclosure statement that complies with 21 C.F.R. §101.13(h), (i.e., See "nutrition information for fat content"). Furthermore, whole or chopped walnuts do not meet the minimum 10 percent nutrient contribution requirement in 21 C.F.R. §101.14(e)(6). However, walnuts contain about 9 percent of the Daily Value per reference amount customarily consumed (RACC) for protein and about 8 percent of the Daily Value per RACC for dietary fiber. FDA intends to consider exercising enforcement discretion as to this requirement because the levels of protein and dietary fiber in walnuts are very close to the 10% level.

Pursuant to this letter, we will immediately begin considering the exercise of our enforcement discretion for the above-referenced health claims and applicable disclosure statement on the label or in the labeling of whole or chopped walnuts. We will be posting this letter on our website or otherwise providing guidance to the public regarding our advice in this letter.

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Within 60 days of the date of this letter, we plan to issue another letter explaining our decision on your petition in more detail.

Sincerely Yours,


for Christine L. Taylor, Ph.D.

Director
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition