FDA Intends to Reevaluate the Scientific Evidence for Four Currently Permitted Health Claims

On December 21, 2007, the Food and Drug Administration (FDA) published a notice in the Federal Register announcing the opportunity for public comment on its intent to reevaluate the scientific evidence for four currently-permitted health claims. The health claims in question include two FDA-approved health claims—soy protein and risk of coronary heart disease and dietary lipids (fat) and cancer—as well as two qualified health claims that FDA has permitted through the exercise of its enforcement discretion—antioxidant vitamins and risk of certain cancers and selenium and certain cancers. FDA has indicated that it is reevaluating the scientific basis for these health claims because of new scientific evidence for these substance-disease relationships. FDA has stated that the new scientific evidence may weaken the substance-disease relationship for the approved health claims and may strengthen or weaken the substance-disease relationship for the qualified health claims.

Under the Nutrition Labeling and Education Act of 1990 (NLEA), FDA was directed, among other things, to issue regulations permitting the use of health claims in the labeling of foods, including dietary supplements, after such claims were reviewed and authorized by FDA. The NLEA amended the Federal Food, Drug, and Cosmetic Act to permit any person to petition FDA for a health claim regulation. The standard that FDA uses to evaluate the petition is whether, based on the totality of the publicly available scientific evidence, there is "significant scientific agreement" (SSA) that the claim is supported by such evidence. FDA approved the health claims for soy protein and risk of coronary heart disease and dietary lipids (fat) and cancer after concluding that the evidence supporting those claims met the SSA standard.

After a federal court of appeals concluded that the First Amendment does not permit FDA to reject health claims that do not meet the SSA standard, if a disclaimer could render the claim truthful and nonmisleading by characterizing the level of scientific evidence underlying the claim, FDA established procedures for allowing the use of qualified health claims through the exercise of its enforcement discretion. Through that process, FDA permitted qualified health claims for antioxidant vitamins and risk of certain cancers and selenium and risk of certain cancers.

FDA now states, however, that evidence regarding these four health claims has evolved such that the agency intends to reevaluate these claims.

2 Id. FDA has defined the term “substance” by regulation to mean “a specific food or component of food”. 21 C.F.R. § 101.14(a)(2).
7 CFSAN, FDA, "FDA's Implementation of ‘Qualified Health Claims’: Questions and Answers" (May 12, 2006).
I. Soy Protein and Risk of Coronary Heart Disease

On October 26, 1999, FDA by regulation authorized the use of certain health claims that associate diets that are low in saturated fat and cholesterol and that include soy protein with reduced risk of coronary heart disease, e.g., “25 grams of soy protein a day, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of food] supplies __ grams of soy protein.” FDA states in the December 21, 2007 Federal Register notice that since the time it authorized these health claims, numerous studies have evaluated this substance-disease relationship and the findings of these studies are inconsistent. Specifically, FDA references a July 2005 Agency for Healthcare Research and Quality (AHRQ) report that concluded that soy products appear to exert a small benefit on low-density lipoprotein (LDL)-cholesterol. Because that report included studies that evaluated substances in addition to soy protein, such as isoflavones, FDA states that it is not clear whether any benefit of soy products is attributable to soy protein – the subject of the current health claim. As a result of this additional scientific evidence, FDA says it intends to evaluate whether the totality of the evidence on soy protein and the risk of coronary heart disease continues to meet the SSA standard.

II. Dietary Lipids and Cancer

FDA authorized the use of certain health claims for dietary lipids (fat) and cancer risk on January 6, 1993, e.g., “Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers.” FDA states in the December 21, 2007 notice, however, that the Institute of Medicine (IOM) of the National Academy of Sciences recently conducted a review of the relevant scientific literature and concluded that the association between diets high in fat and increased cancer risk has been weakened by recent epidemiological studies. In light of that IOM report, FDA intends to reevaluate the scientific evidence on dietary lipids and cancer risk to determine if the totality of the scientific evidence continues to meet the SSA standard to support the current health claim.

III. Qualified Health Claims About Cancer Risk

FDA also stated its intent to reevaluate the scientific evidence underlying two qualified health claims. Both claims were permitted through letters of enforcement discretion issued by FDA in 2003, and both concern the association between a substance and cancer. The first qualified health claim at issue concerns antioxidant vitamins—vitamins E and C—and the risk of certain cancers, e.g., “Some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain

9 21 C.F.R. § 101.82(e).
11 21 C.F.R. § 101.73(e). Unlike the health claims for soy protein, antioxidant vitamins, and selenium—which involve the favorable association of consuming a substance and a decreased risk of disease—the authorized claims for dietary lipids involve the unfavorable association of consuming a substance with an increased risk of disease.
forms of cancer. However, FDA has determined that this evidence is limited and not conclusive.”\textsuperscript{13} The second concerns selenium and certain cancers and anticarcinogenic effects, e.g., “Selenium may reduce the risk of certain cancers. Some scientific evidence suggests that consumption of selenium may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive.”\textsuperscript{14}

In announcing its intent to reevaluate these qualified claims, FDA references a May 2006 AHRQ report on multivitamin/mineral supplements and the risk of chronic disease, noting that the report identified no studies on the efficacy of vitamin C supplements and cancer risk, that the strength of the evidence for vitamin E on cancer risk is “very low,” and that the strength of such evidence for selenium is “low”.\textsuperscript{15} FDA states that it intends to consider whether the evidence continues to support the claims and if so, “whether the qualified health claim language should be modified to reflect a stronger or weaker relationship”.\textsuperscript{16} It is not clear from FDA’s announcement, however, which way the agency is considering modifying the claims on antioxidant vitamins and which way it is considering modifying the claims for selenium.

In addition, as part of its reevaluation of the scientific evidence for the association between dietary lipids, antioxidant vitamins, and selenium and a reduced cancer risk, FDA indicates that it intends to consider claim language that reflects specific types of cancer. Currently the permitted claim language is not cancer-specific and refers to “some types of cancer” or uses similar language.

FDA’s reevaluation of these currently-permitted health claims could have serious implications for food and dietary supplement companies presently using or considering the use of such claims. Conversely, companies marketing higher-fat products may welcome the agency’s reconsideration of the current claim linking dietary fat and cancer risk. It is also notable that this notice follows FDA’s recent proposal to prohibit most currently-permitted omega-3 nutrient content claims,\textsuperscript{17} perhaps indicating a troubling trend of FDA revisiting established claims widely used in the marketplace.

Persons interested in the issues raised by FDA’s notice of its intent to reevaluate the scientific evidence for four currently permitted health claims should consider submitting comments in response to FDA’s notice. Comments are due by February 19, 2008.

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This information is not intended as legal advice, which may often turn on specific facts. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

\textsuperscript{13} CFSAN, FDA, “Antioxidant Vitamins & Cancer” No. 91N-0101, \url{http://www.cfsan.fda.gov/~dms/qhc-sum.html#antioxidant}. The use of this health claim on the label or labeling of a food is subject to eligibility criteria. \textit{id.}

\textsuperscript{14} CFSAN, FDA, “Selenium & Cancer” No. 02P-0457, \url{http://www.cfsan.fda.gov/~dms/qhc-sum.html#selenium}. The use of this health claim on the label or labeling of a food is subject to eligibility criteria. \textit{id.}

\textsuperscript{15} 72 Fed. Reg. at 72739.

\textsuperscript{16} \textit{id.}

\textsuperscript{17} 72 Fed. Reg. 66103, 66103-04 (Nov. 27, 2007), available at \url{http://www.fda.gov/OHRMS/DOCKETS/98fr/E7-22991.pdf}. 
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