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Department of Public Health & Human Services

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GUIDANCE DOCUMENT

Food and Consumer Safety Section

DOCUMENT CODE: WF 170419
DATE: April 19, 2017
SUBJECT: Drug and food claims

Rev.1.19.18

Question

When do claims relating to health for conventional foods render the food a drug?

Answer

Generally, a food or dietary supplement is considered a drug when a statement is made that associates the product with disease (50-31-103(13)(b), MCA). However, there are many exceptions to this generality, and definitive answers are given on an individual or case-by-case basis. The purpose of this document is to provide guidance about properly classifying health-related claims associated with foods.

Background

A claim is a statement, name, or phrase on a product label or promotional material that purports some outcome on a human body or trait possessed, by the food. When public health officials assess claims, a balance must be met between the consumer's lawful right to truthful and forthright information about products, and the manufacturer's constitutional right to freedom of speech.

Sometimes food manufacturers will associate their product or ingredients with mitigation of health ailments, conditions, or benefits. When this happens, health officials must investigate the claims to ensure the product has not crossed the legal threshold of becoming a drug, within the meaning of the law. This document provides guidance about the difference between a food and drug and use of claims.

Food establishment operators are strongly urged to avoid any and all health-related claims that are absent significant scientific agreement about the claim. Exactly what constitutes significant scientific agreement is detailed in the December 20, 1999 FDA document titled "Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements." This procedure is part of Montana's food standards in 37.110.101 (1)(j), ARM, which references federal codes 21 CFR 101, sections 14 and 70.

Rule Interpretation

There is no easily discernable line that is crossed when a conventional food becomes a drug. Decisions on this topic are made on a case-by-case basis because claims vary widely in scope and subtlety. However, the following guidelines may assist in determining how to classify a product when a claim is made with a conventional food.

CLAIM SOURCE

Claims that are subject to review and enforcement are commonly found on product labels and promotional materials. Promotional materials include advertisements and information posted on the internet, printed brochures, or other media outlets. Legal reference for this item are found in various sections of the Montana Food, Drug and Cosmetic Act, but is often within the scope of 50-31-107, 202, or 203, MCA.

NUTRIENT CLAIMS

Nutrient claims are a direct or implied statement about the nutrient level in a food. Terms often associated with nutrient claims are: "healthy," "antioxidant," "good source of …," "high potency," low in saturated fat," "no sugar," "no fat," "less fat," "reduced fat," less sugar," etc. More often, conventional foods that make nutrient claims are not classified as drugs, but must provide an accurate "Nutrition Facts" information panel on their product label, along with the other required product label information.

HEALTH CLAIMS

Health claims link the nutrient in a food with a health effect. To remain a conventional food requires significant scientific agreement for the claim. One study does not meet this threshold. An example of a claim that has significant scientific agreement is: "diets low in sodium may reduce the risk of high blood pressure."

STRUCTURE/FUNCTION CLAIMS

A structure/function claim is a phrase, statement, or terminology used on a product label, advertisement, or promotional material that is not a disease claim, but explicitly or implicitly indicates the product is intended to affect bodily structure or function in humans through an ingredient, ingredients, or nutrient content of the food. In conventional foods, the structure/function effects are derived from the nutritive value of the product. For dietary supplements, the structure/function effects are derived from either or both the nutritive value and/or non-nutritive value of the product.

FDA does not require conventional food and dietary supplement manufacturers to notify FDA about structure/function claims prior to marketing products. However, dietary supplement manufacturers must submit such claims and contextual circumstances to FDA within 30 days after marketing. If a dietary supplement label includes such a claim, the label must include a disclaimer that FDA has not evaluated the claim. The disclaimer must also state that the product is not intended to diagnose, treat, cure or prevent any disease. Conventional foods are not required to submit claims to FDA, or include labeling disclaimers for structure/function claims.

However, state and federal Food, Drug and Cosmetic Acts require that all structure/function claims not be false or misleading representations about the product or its ingredients (50-31-107, MCA). Prior to making any structure/function claim, the operator is strongly advised to be prepared to provide written, reliable and valid scientific facts from qualified experts to defend any and all structure/function claims, preferably with significant scientific agreement. The operator will likely be asked to defend the structure/function claim during the state wholesale food pre-licensing process. The operator should also be prepared for possible challenges from concerned consumers, or local regulatory authorities during inspections. This is done not only for consumer protection, but assisting license holders from inadvertently making false or misleading claims, which could prove costly.

The following is an example of costly claims: In 2008, Airborne Health, Inc., of Bonita Springs, Florida agreed to pay up to $30 million to settle a private class-action lawsuit, Federal Trade Commission charges, and court judgment involving 32 states. This was because the firm did not have

adequate evidence to support advertising claims for its dietary supplements called "Airborne." From the $7 million states' settlement, Montana received approximately $150,000. One of the products exhibited in the State of Montana's complaint against the firm was a label for Airborne lemon-lime dietary supplement. A portion of that label reads: "The original immune-boosting tablet that helps your body fight germs.†" … "† These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."

This case shows that manufacturers should be careful when making claims.

Examples of structure/function claims in conventional foods are "calcium builds strong bones," or "fiber maintains bowel regularity," or "antioxidants maintain cell integrity." As previously stated, food establishment operators are strongly urged to avoid any and all health-related claims that are absent significant scientific agreement about the claim.

DISEASE CLAIMS

A disease claim is a phrase, statement, or terminology used on a product label, advertisement, or promotional material that explicitly or implicitly indicates the product is intended to diagnose, cure, mitigate, treat, or prevent damage to a body organ, body part, body structure, or body system in humans or other animals. However, a disease claim does not include diseases resulting from a deficiency of nutrients that are essential to a healthy body, such as scurvy and pellagra.
Conventional foods can make a disease claim, **IF** the health effects are from the nutritive value of the food, **AND** there is significant scientific agreement about the claim. Examples of claims are: "Low-fat diets rich in fiber containing grain products, fruits, and vegetables may reduce the risk of some types of cancer," or "adequate calcium throughout life may reduce the risk of osteoporosis."

QUALIFIED HEALTH CLAIMS

Court decisions have allowed for the inclusion of a lower food-drug threshold than significant scientific agreement. Qualified health claims have been adjudicated in the courts to set precedent, but they are assessed on a case-by-case basis. The idea behind the precedent is to allow some food products to still make health claims, even though there may not be significant scientific agreement about the effect, but there is publicly available scientific evidence.

In other words, the claim must be based on ALL publicly available scientific evidence, but does not have to be significant scientific agreement.

To gain this status, an applicant must petition the FDA to make a "Qualified Health Claim," and receive a "Letter of Enforcement Discretion" from that agency. If a party is interested in pursuing this avenue, below is a link to frequently asked questions about this topic:
Qualified Health Claims: Questions and Answers

A list of already acceptable qualified health claims may be found at the following FDA webpage links:
Claims: Qualified Letters of Enforcement

SIGNIFICANT SCIENTIFIC AGREEMENT

For additional answers about what constitutes "significant scientific agreement," please use the following FDA link:
Significant Scientific Agreement Guidance

A list of already acceptable significant scientific agreement claims may be found at the following FDA webpage links:
Claims: Significant Scientific Agreement