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Department of Public Health & Human Services

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GUIDANCE DOCUMENT

Food and Consumer Safety Section

DOCUMENT CODE	WF170419
DATE	April 19, 2017
SUBJECT	Drug and food claims

Question

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

Background

Sometimes food manufacturers will associate their product, or ingredients within their product, 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 (50-31-103 (13), MCA). This document provides guidance about the difference between a food and drug and the use of health claims.

Food establishment operators are strongly urged to avoid any and all health 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 bright line that is crossed when 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:

1. CLAIM SOURCE: Claims that are subject to review and enforcement are commonly found on product labels and promotional materials. The 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, MCA, and 50-31-202, MCA, or 50-31-203, MCA.
2. 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.

3. 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."
4. STRUCTURE/FUNCTION CLAIMS: Structure/function claims in conventional foods can make a disease claim, **IF** the health effects are from the nutrition value of the ingredient, **AND** there is significant scientific agreement about the claim. An example of such a claim: "Low-fat diets rich in fiber containing grain products, fruits, and vegetables may reduce the risk of some types of cancer."
5. 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: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-fdas-implementation-qualified-health-claims
6. SIGNIFICANT SCIENTIFIC AGREEMENT: For additional answers about what constitutes "significant scientific agreement," please use the following FDA link: https://www.fda.gov/food/food-labeling-nutrition/authorized-health-claims-meet-significant-scientific-agreement-ssa-standard

Legal Reference
37.110.101 (1)(j), ARM