

FDA Issues Warning Letters on Combination Dietary Supplement/OTC Drug Products

On October 28, 2008, the Food and Drug Administration (“FDA”) issued two warning letters regarding over-the-counter (“OTC”) products that combine aspirin with a dietary supplement into a single pill. One product combined low-dose aspirin and phytosterols, while the other combined low-dose aspirin with calcium.

The two letters state similar legal arguments. The FDA took the following positions:

The products are unapproved “new drugs.”

- In relevant part, the Federal Food, Drug, and Cosmetic Act (“FFDCA”) prohibits the sale of “new drugs” unless (1) the FDA has approved the product under a new drug application or abbreviated new drug application, or (2) for certain OTC drugs, the product meets the requirements of an agency-issued “monograph,” which would include requirements for formulations and claims. Under the FFDCA, for a product to be a new drug, it must first meet the statutory definition of a “drug.”

The FFDCA defines a drug as, among other things, products intended to prevent or treat disease or affect the body’s structure or function. The FDA contended that the products at issue meet this definition because (1) the presence of aspirin and product claims based on aspirin indicate intended uses for the entire products as pain relievers and as preventive measures or treatment for cardiovascular disease, and (2) beyond

pain and heart-related claims based on aspirin, the products make other claims that indicate an intent to treat or prevent osteoporosis and heart disease (e.g., “helps strengthen bones to fight osteoporosis,” “Phytosterols to help lower bad cholesterol”). The FDA also posited that disease prevention and treatment claims attributed specifically to calcium and phytosterols render the ingredients “active drug ingredients” under the FFDCA, thereby furthering the product’s status as a drug. After establishing an argument that the products are “drugs,” the FDA posited that because the products are not sold pursuant to the FDA’s drug regime (i.e., pursuant to a drug application or OTC monograph), the products constitute illegal, unapproved new drugs.

Because use of the products requires physician supervision, OTC sales are not appropriate.

- The FDA stated that heart-related claims as well as the dosage of aspirin in the products indicated that the products require physician supervision, and therefore, cannot be sold over-the-counter. The FDA pointed to claims such as, “Aspirin Protects Your Heart by Keeping Your Blood Flowing Freely.” It also pointed to label statements referencing the American Heart Association, which recommends aspirin treatment for cardiovascular disease (e.g., “For more information on how to fight heart disease and stroke, visit the American Heart Association website at www.americanheart.org”). Regarding the aspirin dosage, the FDA noted that the recommended dosage for both products falls within the dosage

allowed for professional labeling (*i.e.*, labeling for doctors and healthcare professionals) and not the dosage allowed under the monograph for OTC sales directly to consumers.

The products are misbranded.

- The FDA stated that both products are misbranded because the use of products for benefits related to osteoporosis and cardiovascular disease require physician supervision, and therefore, adequate directions cannot be written for OTC consumer use. The FDA also stated that the products were misbranded because the warnings provided are inadequate and contradictory. The FDA noted, for instance, that “Drug Facts” panels on the products specify that consumers should discontinue use and consult a doctor if pain worsens or lasts more than ten days, but “Supplement Facts” panels include directions for daily use, without mentioning any limitations on duration of use.

The FDA previously issued warning letters in 2001 regarding similar combination dietary supplement and OTC drug products. Those letters took similar stances that the products were illegal new drugs and misbranded. The letters targeted two products promoted for joint health and pain relief and one promoted as a sleep aid and pain reliever. One of the joint products combined acetaminophen with glucosamine sulfate; the other combined acetaminophen with glucosamine sulfate and chondroitin sulfate. The sleep aid combined acetaminophen and melatonin.

By the time the FDA issued the latest letters, one of the targeted products had been on the market for approximately six years, and the other had been on the market for at least four months. This delay prompted much speculation as to whether the FDA would amend its policy on combination dietary supplements and OTC drug products. Earlier this month, members of the

House of Representatives Energy and Commerce Committee requested information on the marketing of the targeted products and, in June, the trade group, the American Herbal Products Association, sent a letter to the FDA requesting clarification on the agency’s policy on combination OTC drugs and dietary supplements.

The FDA’s arguments in its latest letters and the 2001 letters are debatable. The arguments raise, for instance, significant questions under the First Amendment commercial speech doctrine (including the case, *Pearson v. Shalala*), questions of general internal inconsistency (*e.g.*, that claims for preventing osteoporosis require professional labeling even though the health claims regime allows consumer-directed labeling), and questions about how closely claims must track the model language provided in the FDA’s approved health claims. These debates, however, are academic if and until a party challenges the FDA in court. For now, it is clear that if a company chooses to launch a combination dietary supplement/OTC drug in a single pill or other single form of administration, it likely will draw enforcement action.

It is important to note that even with the FDA’s policy firmly in place, all routes to product synergy are not foreclosed. The FDA’s position on combination products does not definitively foreclose, for instance, the possibility of selling separate, but complimentary OTC drug and dietary supplement products. As U.S. consumers appear to move toward a healthcare mindset focused on preventive and evidence-based self-care, companies may want to explore new routes for marketing OTC health and nutritional products.

KELLEY DRYE & WARREN LLP

Kelley Dye’s team of Food and Drug lawyers strives to integrate our clients’ business strategies with FDA compliance and to help resolve regulatory enforcement matters when they arise. Working side-by-side with

business development and marketing professionals, we provide comprehensive regulatory counseling and assist in developing products, labels, and promotional materials that achieve our clients' goals without running afoul of regulatory requirements. With close knowledge of FDA's enforcement priorities and deep experience with the FTC's regulation of advertising, our team can provide comprehensive legal advice with an eye towards giving clients a competitive edge.

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