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Supplement/OTC Combos Have Precedents In Other Categories, Firms State

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Executive Summary

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"FDA's implementing regulations define, in part, 'combination products' to include 'a product comprised of two or more regulated components, *i.e.*, drug/device, biologic/device, drug/biologic...that are physically, chemically or otherwise combined or mixed and produced as a single entity," B.F. Ascher states.

"While there is no similar statutory provision specifically acknowledging the existence of drug/ dietary supplement combination products, the more important observation is that there is no statutory prohibition against the marketing of such products," the firm continues.

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"In point of fact, there is simply *no* provision in the [FD&C] Act, nor has the FDA even attempted to manufacture one, that *prohibits* the marketing of a drug/dietary supplement combination product as long as that product complies with the relevant laws and regulations applicable to the individual components of the combination," B.F. Ascher maintains.

The letters respond to Oct. 16 warning letters regarding B.F. Ascher's ***Melagesic PM*** (acetaminophen and melatonin) and Omni Nutraceuticals' ***Inholtra Joint Pain Caplets*** and Inholtra Joint Pain Plus Caplets (acetaminophen and glucosamine and/or chondroitin sulfate) ([1] "OTC/Dietary Supplement Combos Cited In FDA Warning Letters" — *"The Tan Sheet,"* Oct. 22, 2001, p. 3).

Arent Fox Kintner Plotkin & Kahn (Washington, D.C.) and Frommer Lawrence & Haug (New York) submitted the letters to FDA on behalf of B.F. Ascher and Omni, respectively.

Due to the legal marketing of other combination products, B.F. Ascher maintains the agency's "assertion that Melagesic PM cannot be marketed as a combination of a drug and dietary supplement is... contrary to this long history of Congressional and agency recognition of combination products."

The companies indicate the hybrid category most closely related to a drug/dietary supplement combination is cosmetic/drugs. Both Omni and B.F. Ascher's letters refer repeatedly to the product class as setting a precedent for the marketing of the Melagesic and Inholtra products.

Omni specifically notes that FDA has recognized anti-perspirants/deodorants, sunscreens/suntan products and anti-dandruff shampoos as combinations items that "can lawfully be marketed."

D.C. attorney Peter Barton Hutt (Covington & Burling) also has cited cosmetic/drugs as models for possible drug/supplement combinations. During a speech at a meeting on functional foods in 1999, he asserted such products could be marketed using dual labeling ([2] "The Tan Sheet" May 24, 1999, p. 16).

Omni additionally states that the marketing of two other drug/supplements for several years without agency action shows the combination is appropriate, citing ***Luden's Menthol Throat Drops*** with echinacea and vitamin C and ***Aspirin Regimen Bayer*** 81 mg with calcium.

The Luden's line was recently acquired by Pharmacia ([3] "Pharmacia Luden's Acquisition Fuels Presence For Coming Cough/Cold Season" — *"The Tan Sheet,"* Sep. 10, 2001, p. 6). However, in 1999, when the brand was owned by Hershey Foods, FDA sent the firm a "courtesy letter" stating the drops could not be categorized as dietary supplements since they are not intended for ingestion ([4] "Luden's Echinacea Throat Drops Are Not Dietary Supplements, FDA Says" — *"The Tan Sheet,"* Dec. 13, 1999, p. 7). It does not appear FDA has acted on the issue since.

With regard to the Bayer product, while labeling notes "each caplet provides...10% (100 mg) of the daily value of calcium," no therapeutic claims are made in reference to the calcium, with the nutrient described solely as the caplet's "buffered base." Bayer said the product is covered under the internal analgesic tentative final monograph.

Along with maintaining the inclusion of dietary supplement and OTC drug ingredients in the same product is legal, B.F. Ascher and Omni also state their products' labeling complies with the regulations governing both supplements and OTCs.

Omni asserts its Inholtra products' labeling for acetaminophen complies with the OTC internal analgesic monograph's requirements and "other applicable OTC drug labeling requirements," while the labeling for the glucosamine/chondroitin ingredients complies with the provisions of the Dietary Supplement Health & Education Act.

However, Omni also contends that "the structure/ function rule applies exclusively to claims made in the labeling of dietary supplements. It does not apply to claims made for combination OTC drug-dietary supplements, such as the Inholtra products, where there is a drug ingredient as well as a dietary ingredient in the product's formulation."

Similarly, B.F Ascher notes Melagesic label was designed to comply with the internal analgesic tentative final monograph and other regs governing acetaminophen-containing drugs, "with appropriate modifications to accommodate the dual nature of the product."

"The label was not designed to comply with the monograph for OTC nighttime sleep-aid products because the product is not regulated under this monograph," the letter says.

Despite their disagreement with FDA's position, both companies note they will make certain changes to their products' labeling to address some of the agency's concerns.

Omni will remove the words "long term" from its Inholtra products' nutritional support statement on joint health and will make the statement "stop use and ask a doctor if...pain gets worse or lasts more than 10 days" more prominent in labeling. The revisions respond to FDA's assertions people could take the products for joint health for longer than 10 days, which is contra-indicated for acetaminophen without medical supervision.

The company also will add a statement advising that physicians be consulted when giving the product to children under age three.

At the next label printing, B.F. Ascher notes it will include a statement clarifying the melatonin in Melagesic PM is meant for "occasional sleeplessness." The new label also will state: "If sleeplessness persists continuously for more than 10 days, consult your physician. Insomnia may be a symptom of a serious underlying illness."

Both parties additionally expressed an interest in meeting with FDA. To date, no meeting has been scheduled.