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Second Circuit Affirms Win for Defendants in Challenge to Glucosamine Labeling on Federal Preemption Grounds

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- Last week the United States Court of Appeals for the Second Circuit affirmed a grant of summary judgment for Defendants Walgreen Co. and International Vitamin Corporation (IVC) on preemption grounds in a case involving dietary supplement labeling. IVC manufactured and Walgreens sold a glucosamine dietary supplement product which Plaintiffs argued was misleadingly labeled in light of the product formulation.
- Plaintiff alleged that Defendants should have declared the dietary ingredient as “glucosamine hydrochloride **and** potassium sulfate” (bold added) and not as “glucosamine hydrochloride potassium sulfate.” This argument hinged on the distinction between glucosamine sold as a single crystal form in contrast to a blended form. The single crystal form consists of a glucosamine-sulfate-potassium-chloride salt, while the blend consists of a mixture of a glucosamine-hydrochloride salt and potassium-sulfate salt. In an aqueous solution (as with the human body), both forms dissociate into the same glucosamine, sulfate, potassium, and chloride constituents.
- Dietary ingredients like glucosamine for which FDA has not established a Reference Daily Value or a Daily Reference Value must be declared by their common or usual name which, the court stated, is to be determined by testing the ingredient with a validated method of identification. In the absence of appropriate AOAC methods, “other reliable and appropriate analytical procedures” may be used, although FDA has indicated that, where available, it expects official compendial methods such as the U.S. and European pharmacopoeias to be used.
- It was uncontested that both forms of glucosamine (single crystal and blend) are consistent with the monographs for “Glucosamine Sulfate Potassium Chloride” in the U.S. and European pharmacopoeias. The Federal Food, Drug, and Cosmetic Act (FDCA) contains an express preemption provision which forbids states from establishing food labeling standards that are “not identical” to certain federal food labeling requirements, including the requirement that ingredients be identified by their common or usual names. Therefore, because the dietary ingredient declaration was consistent with the monographs in the pharmacopoeias, and such pharmacopoeias contained “reliable and appropriate analytical procedures” endorsed by FDA, the Court held that “glucosamine hydrochloride potassium sulfate” was the common or usual name under the federal regulations and that the name was insulated from legal challenge based on the FDCA’s labeling preemption provision.

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