



Preemption in Dietary-Supplement Litigation: FDA Remains Master of the “Common or Usual Name”

by Megan Olsen and Katie Bond

A recent decision by the U.S. Court of Appeals for the Second Circuit assures that “the FDA is to be the master of the ‘common or usual name’ of dietary ingredients.” *Jackson-Mau v. Walmart*¹ echoed the reasoning of the Ninth Circuit’s decision in *Hollins v. Walmart Inc.*,² holding that FDA requirements applied to the identification of ingredients both inside and outside the Supplement Facts panel.

The Second Circuit’s decision, more so than the Ninth Circuit in *Hollins*, makes important procedural strides for the preemption doctrine. In *Jackson-Mau*, the court referenced an almost never used (and likely little known) FDA regulation that companies should take note of when invoking federal preemption as it sheds more light on the scope of the Food Drug and Cosmetic Act’s (FDCA) express labeling preemption clause for food and dietary supplements.³ To preserve uniformity of federal labeling standards, FDCA § 403A prohibits states from “directly or indirectly” establishing any state labeling requirement that is “not identical to” a federal labeling requirement.

The FDA regulation highlighted in *Jackson-Mau*—21 C.F.R. § 100.1—governs a petition process allowing States to petition the FDA for an exemption to the FDCA’s § 403A(a) preemption clause. Under FDCA § 403A(b), “where a State requirement has been preempted under section 403A(a) of the act, the State may petition the agency for an exemption” and “[t]he agency may grant the exemption, under such conditions as it may prescribe by regulation”⁴ Of relevance to the Second Circuit in *Jackson-Mau* and other class actions involving preemption, the regulation defines when a state labeling requirement is “not identical” to a federal labeling requirement. A state requirement is “not identical” where “the State requirement directly or indirectly imposes obligations or contains provisions concerning the composition of labeling of food” that “[a]re not imposed by or contained in” or that “[d]iffer from those specifically imposed by or contained in” the FDCA and its implementing regulations.⁵ The Second Circuit took note of this language and determined that “[i]n other words, the FDCA preempts ‘any state law that provides for labeling requirements that are not *exactly the same* as those set forth in the FDCA and its regulations.’”⁶

¹ 115 F.4th 121 (2d Cir. Aug. 16, 2024).

² 67 F.4th 1011 (9th Cir. 2023). See also Katie Bond & Samuel Butler, *Which Is to Be Master? A Preemption Win in the Dietary Supplement Space*, WLF LEGAL PULSE, May 18, 2023, <https://www.wlf.org/2023/05/18/wlf-legal-pulse/which-is-to-be-master-a-preemption-win-in-the-dietary-supplement-space/>.

³ 21 U.S.C. § 343-1; FDCA § 403A.

⁴ 21 C.F.R. § 100.1(a)(2).

⁵ 21 C.F.R. § 100.1(c)(4).

⁶ 115 F.4th at 128 (citing *Critcher v. L’Oreal USA, Inc.*, 959 F.3d 31, 35-36 (2d Cir. 2020)).

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Courts have recognized that imposition of an additional requirement that governs how a label statement may be made is preempted.⁷ However, the FDA regulatory language gives force to those arguments that preemption is not just applicable to state laws that would mandate conflicting labeling requirements. It also applies to state laws attempting to impose any obligation on the type of labeling that is governed by the FDCA's express preemption clause that is different from that in the FDCA or FDA implementing regulations. In other words, as previous precedent has held, States cannot add elements to the requirements for a compliant structure/function claim, for example, or in the case of *Jackson-Mau*, require different methods to be used to identify an ingredient than those methods permitted by FDA.

In *Jackson-Mau*, the defendant used an "FDA-endorsed compendial identity test" to identify the active dietary ingredient in the product as "Glucosamine Sulfate Potassium Chloride" in the product's Supplement Facts panel. The front of the bottle displayed the name "Glucosamine Sulfate." The plaintiff argued that the defendants' compendial methods were inappropriate because they cannot distinguish between different types of glucosamine and that "glucosamine sulfate potassium chloride" is not the "common or usual name" for "blended glucosamine according to the non-compendial methods of her own expert witness."⁸ The court disagreed, finding the fact that the glucosamine-based dietary ingredient passed the compendial identity tests for "glucosamine sulfate potassium chloride" dispositive as "[t]he FDA gives manufacturers, the ability to choose among methods that 'they believe will give results consistent with methods used by [the] FDA'" and "[t]he FDA prefers compendial over non-compendial methods for determining the accuracy of ingredient labeling."⁹

Had the court determined that the compendial methods were inappropriate methods to identify the "common or usual name" of the dietary ingredient in reliance on the plaintiff's arguments that the defendant had exploited a "blind spot" in the compendial methods to "defraud the consumer," the court would have been imposing requirements on how a dietary supplement company is required to determine the "common or usual name" of an ingredient that were different (*i.e.*, "not identical") to the federal requirement. Where the federal requirement allows a manufacturer to identify a dietary ingredient's common or usual name by using a compendial method (which the defendant did in this case), any requirement imposed by the plaintiff to determine if a compendial method is "appropriate" is preempted because the FDCA does not require that type of analysis.

The Second Circuit, like the Ninth Circuit, also looked at how federal preemption affected the use of the term "glucosamine sulfate" to identify the ingredient on the front of the product, outside the Supplement Facts panel. The plaintiff argued that preemption did not apply to ingredient identity statements outside of the Supplement Facts panel because the federal requirements were only specific as to the Supplement Facts. Here, the court's analysis aids future defendants in understanding not only what is "not identical" but also when a state labeling requirement is "of the type required" by the FDCA. The FDCA's preemption provision sweeps broadly to govern the name under which a supplement may be offered for sale. While the court noted that the FDA had not promulgated regulations implementing this requirement, the court determined that they could not find a term to be the appropriate "common or usual name" on one section of the label and not another.¹⁰ Plaintiff's

⁷ See, *e.g.*, *Ferrari v. Vitamin Shoppe Indus. LLC*, 70 F.4th 64, 73 (1st Cir. 2023) ("If the manufacturer's label satisfies [federal] requirements, consumers may not attack the structure/function claim under state law"); *Greenberg v. Target Corp.*, 985 F.3d 650, 656 (9th Cir. Jan. 13, 2021) ("[I]f the defendant's [product description] meets the FDCA's three requirements for a structure function claim, then any state law claims challenging that claim fall to the wayside.").

⁸ 115 F.4th at 129.

⁹ *Id.* at 130.

¹⁰ *Id.* at 131.

theory would have required that the court impose different or additional labeling requirements for the “common or usual name” of an ingredient depending on where on the label that name appeared.

Also of note in *Jackson-Mau* is the court’s reference to cosmetic federal labeling requirements and the relevance to interpreting the express preemption provision for food/dietary supplement labeling. The court noted that its determination to foreclose the use of compendial methods different from that recognized by FDA was consistent with “an analogous FDCA preemption case” holding that “the FDCA foreclosed the state law claims [for cosmetics packaging]” because “to avoid liability under the consumer’s mislabeling theory, the defendant would have to make packaging disclosures ‘in addition to’ the requirements already imposed by the FDCA and its regulations.”¹¹ One wonders how such precedent squares with or might impact state disclosure laws like California’s Prop 65.

FDA preemption cases are experiencing a bit of a resurgence, with first the Ninth Circuit and now the Second Circuit following suit to foreclose state law requirements that are not identical to the type of labeling requirements governed by the FDCA.

¹¹ *Id.*