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Pending FDA Cosmetics Review Allows Class Action Defense

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(February 3, 2023, 5:03 PM EST)

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In late December 2022, President Joe Biden signed into law the Modernization of Cosmetics Regulation Act, a significant overhaul of the U.S. Food and Drug Administration's regulatory framework for cosmetics.

MOCRA amends Chapter VI: Cosmetics of the Federal Food, Drug and Cosmetic Act and constitutes the first expansion of the FDA's authority over cosmetics since the FDCA's enactment in 1938.

Among its many provisions, MOCRA specifically directs FDA to study, report on and regulate two common types of cosmetic ingredients: perfluoroalkyl and polyfluoroalkyl substances, or PFAS, and talc.

Use of PFAS and Talc in Consumer Protects

PFAS are synthetic chemicals that are used in a variety of consumer products, including cosmetics, because of their water- and oil-resistant properties.

Notably, PFAS do not easily biodegrade, and as a result, have become known colloquially as forever chemicals. Though PFAS have recently received negative attention due to California's and other states' plans to ban them from cosmetics products,[1] the FDA has recognized that there is no conclusive evidence they pose a health risk to consumers — particularly given the low levels present in cosmetics products.[2]

Talc is an organic substance which is mined from the earth and is used in a number of consumer products because of its slipperiness and softness. In some circumstances, talc has been found to be geologically commingled with other minerals, some of which may be asbestos.

There has been a significant increase in PFAS-related and talc-related litigation over the past several years, especially in the form of consumer class actions alleging that food, beverage and cosmetic labeling falsely and/or misleadingly fails to disclose the presence of PFAS and/or talc in a given product.

To date, these lawsuits have led to mixed results for consumer products manufacturers but have all resulted in significant defense costs.

MOCRA's Directions Regarding PFAS and Talc

MOCRA specifically directs the FDA to assess the use and safety of PFAS in cosmetic products and to analyze the scientific evidence regarding any risks associated with their use in cosmetics.

MOCRA requires the FDA to publicly publish a report summarizing its findings regarding PFAS by Dec. 29, 2025. This dovetails with the FDA's announcement on its website in early 2022 that it was monitoring studies and scientific data relating to PFAS in cosmetics, and would conduct related research, given the limited research on the subject.[3]

In addition, MOCRA directs the FDA to publish a proposed rule establishing and requiring standardized testing methods for detecting and identifying asbestos in talc-containing cosmetics. The rule must be proposed by Dec. 29, 2023, and a final rule must be issued no later than 180 days after the comment period on the proposed rule closes.

Primary Jurisdiction

The combination of MOCRA's express charge to the FDA to investigate and propose rules regarding the use and safety of PFAS and talc in cosmetics products, as well as the FDA's own statements that such investigation is necessary and ongoing, strongly suggests that such guidance and rulemaking is forthcoming.

This development offers cosmetics manufacturers a strong defense to fend off consumer fraud lawsuits challenging PFAS and talc label disclosures.

Specifically, because the FDA is now charged with formally investigating and proposing rules regarding the use and safety of PFAS and talc in cosmetics products, manufacturers may be able to avail themselves of the primary jurisdiction doctrine to stay or dismiss labeling challenges until the FDA completes its review.

Primary jurisdiction is a prudential doctrine that allows a court to dismiss or stay a case pending agency review when it presents a novel or complex issue that implicates the specialized or technical expertise of a regulatory agency.

The doctrine is premised on the theory that the agency charged with regulating the field should be permitted to consider the issue in the first instance before a court weighs in.

Courts typically invoke primary jurisdiction when an agency has indicated that it is actively investigating a technical issue raised in the litigation and that rulemaking or further regulatory guidance on the issue is expected.

In recent years, defendants in consumer fraud actions have found success invoking the primary jurisdiction doctrine when there is evidence that the FDA is actively considering regulating a particular type of ingredient or labeling claim.[4]

For example, many courts granted stays on primary jurisdiction grounds of consumer class actions

challenging use of the term "natural" on food product labels after the FDA issued a request for comment regarding use of that term in labeling.[5] These decisions include the 2019 Hawyuan Yu v. Dr Pepper Snapple Group Inc. case in the U.S. District Court for the Northern District of California.

Similarly, such as in the 2021 DaSilva v. Infinite Product Company LLC case in the U.S. District Court for the Central District of California, courts stayed consumer class actions challenging the labeling of products infused or made with cannabidiol on the grounds that the FDA was actively considering developing regulations for those products.[6]

Most recently, several courts have dismissed, on primary jurisdiction grounds, consumer challenges to the presence of heavy metals in baby foods due to the FDA's announcement of a plan to identify what levels of heavy metals in baby foods are unsafe.[7] For example, last month, the U.S. District Court for the Northern District of New York dismissed In re: Beech-nut Nutrition Company Baby Food Litigation.

In light of this precedent, it seems likely that courts faced with PFAS- or talc-related labeling challenges will be inclined to follow suit to enable the FDA to fulfill MOCRA's charge, thereby providing defendants with, at the very least, some significant breathing room while the FDA does its work.

And once FDA guidance and regulations are released, defendants will likely be well-positioned to defeat PFAS- or talc-related consumer class actions on preemption grounds given FDA's pronouncements on these exact issues.

In sum, MOCRA provides the FDA with new tools and resources to ensure that cosmetic ingredients are safe and effective.

And while the FDA performs its analysis, manufacturers can rely on the doctrines of primary jurisdiction and preemption to fend off PFAS- or talc-related consumer class actions, which seek to require labeling disclosures that may differ from those FDA has in mind.

All told, this is a positive development for consumers and manufacturers, and an important step in promoting uniform labeling requirements for cosmetics containing PFAS and talc.

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[1] See Cosmetic Products: Safety, AB-2771, https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=202120220AB2771.

An Act to Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution, H.P. 1113-L.D. 1503, http://www.mainelegislature.org/legis/bills/getPDF.asp?paper=HP1113&item=5&snum=130; An Act Relating to logistical processes for the regulation of priority chemicals in consumer products, H.B. 1694, https://lawfilesext.leg.wa.gov/biennium/2021-22/Pdf/Bills/House%20Passed%20Legislature/1694-S.PL.pdf?q=20220312190640.

[2] U.S. Food & Drug Admin., Per and Polyfluoroalkyl Substances (PFAS) in Cosmetics (updated Feb. 5, 2022), https://www.fda.gov/cosmetics/cosmetic-ingredients/and-polyfluoroalkyl-substances-pfas-cosmetics.

[3] U.S. Food & Drug Admin., Per and Polyfluoroalkyl Substances (PFAS) in Cosmetics (updated Feb. 5, 2022), https://www.fda.gov/cosmetics/cosmetic-ingredients/and-polyfluoroalkyl-substances-pfas-cosmetics.

[4] Snyder v. Green Roads of Florida LLC, 430 F. Supp. 3d 1297 (S.D. Fla. Jan. 3, 2020).

[5] See, e.g., Kane v. Chobani, LLC, 645 F. App'x 593, 594 (9th Cir. 2016) (staying case on primary jurisdiction grounds pending the FDA's delineation of scope and permissible usage of term "natural" on food product label); Hawyuan Yu v. Dr Pepper Snapple Grp., Inc., 2019 WL 2515919 (N.D. Cal. June 18, 2019) (staying case in light of FDA's open and active proceedings regarding the term "natural"); Rosillo v. Annie's Homegrown, Inc., 2017 WL 5256345 (N.D. Cal. Oct. 17, 2017) (same).

[6] See, e.g., Snyder, 430 F. Supp. 3d at 1308 (staying CBD consumer class action until FDA completed rulemaking on the marketing of ingestible CBD products); Dasilva v. Infinite Prod. Co. LLC, 2021 WL 900642 (C.D. Cal. Mar. 3, 2021) (staying case pending FDA rulemaking regarding the definitions, marketing, and labeling of CBD products); Colette v. CV Scis., Inc., 2020 WL 2739861 (C.D. Cal. May 22, 2020) (same).

[7] See, e.g., In re Beech-Nut Nutrition Co. Baby Food Litig., 2023 WL 350818 (N.D.N.Y. Jan. 19, 2023); In re Gerber Prod. Co. Heavy Metals Baby Food Litig., 2022 WL 10197651 (E.D. Va. Oct. 17, 2022); Kimca v. Sprout Foods, Inc., No. BER-L-002538-22, MTD Order at 4–7 (N.J. Super. Ct. Law Div. Aug. 17, 2022).