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FDA's Bumpus Will Be Principal Deputy Commissioner; Cosmetics Industry Reacts With Congratulations, Questions

by Eileen Francis

Chief scientist Namandjé Bumpus will replace Janet Woodcock as principal deputy commissioner at the US FDA when the latter steps down in early 2024. The Personal Care Products Council says Bumpus will continue to lead MoCRA implementation efforts while a new chief scientist is sought, but those and other details remain fuzzy.

News that US Food and Drug Administration chief scientist Namandjé Bumpus will replace Janet Woodcock as principal deputy commissioner at the US Food and Drug Administration when the latter steps down in early 2024 has cosmetics industry stakeholders reacting with congratulations, as well as questions.

Commissioner Robert Califf announced the move in a 29 November <u>memo to staff</u>, noting Bumpus "will work closely with FDA leadership to develop, advance and implement key public health initiatives, as well as to oversee the agency's day-to-day functions."

He said FDA was fortunate when Bumpus joined the agency in August 2022. "As chief scientist she has overseen and quickly elevated the research foundation, science and innovation that provides vital support for our public health mission," said Califf. He added, "This includes leading the agency's implementation of the Modernization of Cosmetics Regulation Act." (Also see "*US FDA Chief Scientist Bumpus Will Become Principal Deputy Commissioner*" - Pink Sheet, 29 Nov, 2023.)

Bumpus joined the FDA in 2022 from Johns Hopkins and began overseeing MoCRA when FDA announced in early 2023 it would move the Office of Cosmetics and Colors (OCAC) from the Center for Food Safety and Applied Nutrition into the Office of the Chief Scientist as part of an effort to support a new Human Foods Program. (Also see "FDA Announces New Home For

HBW INSIGHT

Cosmetics Under Proposed Food Program Restructuring" - HBW Insight, 1 Mar, 2023.)

According to the Personal Care Products Council, Bumpus will continue overseeing MoCRA activities as the program's "executive sponsor," with plans to "keep steering implementation and ensure continued transparency."

"The plan remains to have OCAC sit under the Office of the Chief Scientist and the Commissioner likely will be looking to hire a new FDA chief scientist to fill that role with the elevation of Dr. Bumpus to principal deputy commissioner," a PCPC spokesperson told HBW Insight. "She would be part of that process and would look to see that any new FDA chief scientist also has a commitment to the cosmetics program."



NAMANDJE BUMPUS WILL ASSUME THE ROLE OF PRINCIPAL DEPUTY COMMISSIONER IN 2024.

John Bailey, an independent advisor for colors and cosmetics at EAS Consulting Group based in Alexandria, VA, is looking for the same in Bumpus' successor. The new chief scientist "will need to understand the regulatory process and also be able to balance risk posed by cosmetics. Cosmetics are overwhelmingly safe," he said.

Bailey, who served formerly as FDA's OCAC director and later VP for science at PCPC, is concerned the leadership change "throws uncertainty into the process" of carrying out the various requirements of MoCRA. Meanwhile, there's significant uncertainty about the cosmetic program restructuring. Bailey's understanding is that the FDA was to finalize a proposal for the move this fall but does not appear to have done so. He said he believes the cosmetics program "still resides within CFSAN."

"I see no sign that additional funds have been allocated" for the move, he said. "This does not appear to be rolling out smoothly."

He hopes Bumpus' successor will make the effort to get well-acquainted with the cosmetics industry as it faces significant new challenges under MoCRA. Those include facility registration and product/ingredient listing with the FDA, which MoCRA requires by 29 December 2023, though the FDA recently announced it would delay enforcement by six months. (Also see "FDA Has Early Holiday Gift For Cosmetics Industry: More Time To Register Under MoCRA" - HBW Insight, 8 Nov, 2023.)

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MoCRA also requires cosmetics companies to maintain adverse event records, report serious adverse events to the FDA, maintain safety substantiation records, and comply with good manufacturing processes once the agency establishes them by way of final rulemaking by 29 December 2025.

Bailey's foremost concern is how the chief scientist addresses safety substantiation under MoCRA. "My biggest worry is with the notion of adequate substantiation of safety for cosmetics. It needs to be reasonable and appropriate and, most of all, accept [Cosmetic Ingredient Review expert panel decisions] as a key part of building the safety dossier," Bailey said.

In a 30 November statement, PCPC president and CEO Lezlee Westine congratulated Bumpus on her new role. "We are so pleased to hear that she will continue to oversee efforts on the implementation of the Modernization of Cosmetics Regulation Act of 2022, and we look forward to continuing to work with her and the agency by providing industry's perspective."

PCPC announced on 15 November that Tom Myers, executive VP for legal and regulatory affairs and general counsel, will succeed Westine as president and CEO in January 2024. (Also see "PCPC Legal Head Tom Myers Steps Into President, CEO Role In 2024" - HBW Insight, 15 Nov, 2023.)

Arlington, VA-based Fragrance Creators Association released a statement on 29 November commending Bumpus' "commitment to advancing public health predicated on best-in-class science, as our members remain dedicated to ensuring we continue to support the agency — for people, perfume, and the planet."

Fragrance Creators president and CEO Farah Ahmed notes the timing of the Bumpus announcement amid the FDA's ongoing work to implement MoCRA. "Fragrance Creators values collaborating with Dr. Bumpus as we continue to serve as a resource to the agency. She had been a thoughtful leader and a scientist of the highest caliber. Personally, as a former FDA employee, I am delighted to see the agency also prioritize diversity – an inspiration for all women, especially women of color – in this role."

Plain Talker, Truth Teller, And A 'Formidable' Scientist

In his memo, Califf said Bumpus has "raise[d] the cache of the FDA's regulatory science within the agency and to the outside world in part by being a champion of plain language, a staunch advocate for truth-telling in public health, and a formidable scientist."

Bumpus has said her interest in health disparities and how to "use science to improve the health of all people" was the lens through which she would lead the agency's cosmetics program. Among her first orders of business was a planned proposed rule to ban formaldehyde and other formaldehyde-releasing chemicals (eg, methylene glycol) as ingredients in hair-smoothing products marketed in the US. ((Also see "*US FDA Chief Scientist Bumpus Takes On Health*

HBW INSIGHT

Disparities, Formaldehyde In Hair Straighteners" - HBW Insight, 19 Oct, 2023.)

Bumpus noted studies showing an increased risk of upper respiratory tract cancers and myeloid leukemias among users of heated hair-straightening products containing formaldehyde, which are often marketed to black women.

The agency announced its intent to issue the proposed rule in the most recent Unified Agenda, a semi-annual list of planned regulatory actions from the Office of Management and Budget. A Notice of Proposed Rulemaking is tentatively slated for publication in the Federal Register in April 2024.

Alexandra Scranton, director of science and research at Missoula, MT-based advocacy group Women's Voices for the Earth, said the group has been encouraged by Bumpus' apparent interest in the formaldehyde-hair straighteners issue, which WVE believes has gone unaddressed by FDA for too long.

"We wish Dr. Bumpus well in her career move at FDA and certainly hope her replacement as chief scientist will maintain the momentum at FDA towards finally banning cancer-causing formaldehyde from these products," Scranton said.

Wade Ackerman, FDA partner at Covington & Burling LLP's Los Angeles office and former senior FDA counsel at the Senate HELP Committee, acknowledged Janet Woodcock leaves large shoes to fill, but said Bumpus "is a great choice" to fill them. "Dr. Bumpus has been a strong chief scientist at FDA, leading agency efforts on a number of fronts, including implementation of the recent legislation overhauling FDA's oversight of cosmetics."

Jessica O'Connell, partner in Covington's DC office, added Bumpus has done an excellent job of starting and leading the implementation of MoCRA, and the attorney is confident about the path forward. "I don't have any immediate concerns about this impacting FDA's speed of implementing MoCRA – we've seen continued efforts from FDA on MoCRA implementation since the legislation passed and I think it's clear that the implementation process is in progress and moving forward."

Kelly Bonner, a trial attorney in Duane Morris LLP's Philadelphia office, also weighed in.

"I think that Dr. Bumpus is an impressive scientist and leader, particularly with respect to MoCRA. I don't think that her elevation will slow MoCRA's rollout; rather, I think FDA is approaching MoCRA with an understanding that it has and will involve a significant regulatory shift for the industry. I hope that her successor will share her focus on implementing MoCRA, as well as her willingness to genuinely engage with and listen to industry voices about how best to implement MoCRA."