Congress of the United States

Washington, DC 20515

April 9, 2025

The Honorable Marty Makary Commissioner U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

Dear Commissioner Makary:

We write to inquire about the status of the proposed ban on formaldehyde in hair products, which was issued in October 2023 due to alarming health findings.

The Food and Drug Administration (FDA) is charged with maintaining public health by ensuring the safety and efficacy of ingredients used in products by consumers across the country from cosmetics to hair products. Despite its documented health risks, formaldehyde, a known carcinogen classified by the International Agency for Research on Cancer (IARC), is widely used in hair relaxers and other chemical hair-straighteners such as keratin treatments, Brazilian blowouts, and chemical straightening creams. Extended exposure to formaldehyde during these treatments has been linked to increased incidences of cancer, respiratory issues, and adverse reproductive outcomes. Of particular concern is the heightened health risk to Black women, who are more likely to receive or provide formaldehyde-based hair treatments, which has a disparate impact on both workers and their customers.

Despite the initial proposal to ban formaldehyde in October 2023 and the proposed rule being moved to the OMB unified agenda in Fall 2024, the action date of March 2025 to further advance this regulatory action has passed. Since Fall 2024, there has been no further movement or concrete next steps regarding the implementation of the ban. This delay is particularly concerning given the established links between formaldehyde exposure and serious health conditions, including myeloid leukemia and hormone-sensitive cancers such as breast, uterine, and ovarian cancer according to the U.S. Department of Health and Human Services and a study conducted by the National Institute of Health in 2022.

In March of 2023, Members of Congress sent a letter to the FDA inquiring about this issue and calling for the FDA to investigate "the potential health threat posed by chemical hair straightening products" to safeguard public health, especially among vulnerable populations. A follow-up letter was sent in August 2024 urging the FDA to finalize the proposed rule banning formaldehyde, address questions surrounding the delay, engage in proactive outreach to stakeholders, and address concerns regarding the prolonged health effects.

As the Food and Drug Administration is now under new leadership, we the undersigned, write to again urge the FDA to provide answers to the following:

- 1. Given the delay, what steps will be taken to finalize the proposed rules outlined on Office of Management and Budget's Unified Agenda?
- 2. Are there any current or upcoming changes to federal regulations that would impact the finalization of the proposed rule?

- 3. How is the FDA prioritizing this issue relative to other regulatory efforts? Are there specific challenges delaying the finalization of the rule?
- 4. Beyond formaldehyde, does the FDA plan to examine other hazardous chemicals commonly found in personal care products? If so, what substances are under consideration?

As the FDA works to address these pressing issues, it is essential to continue to highlight the gravity of formaldehyde exposure, as evidenced by both epidemiological data and laboratory research. Ensuring that regulatory actions align with the best interests of public health remain the goal and we encourage promptly finalizing the proposed rule. We look forward to your timely response.

Sincerely,

Nydia M. Velázquez Member of Congress

Shontel M. Brown Member of Congress

Ayanna Pressley Member of Congress