CHPA® | CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

Taking healthcare personally.

November 10, 2022

Kerri Malinowski Farris
Maine Department of Environmental Protection
Office of the Commissioner
17 State House Station
Augusta, Maine 04333-0181

**RE: Comments on Second Concept Draft for the Maine PFAS in Products Program**

Dear Ms. Malinowski Farris:

On behalf of the Consumer Healthcare Products Association (CHPA), the national trade association representing the leading manufacturers of over-the-counter (OTC) medications, dietary supplements, and consumer medical devices, please accept our comments to the second concept draft for the Maine PFAS in Products Program being developed by the Maine Department of Environmental Protection (DEP). While the Second Concept Draft contains much needed improvements, it also introduces new issues that we cannot support.

**Definition of Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS)**

According to the Second Concept Draft, PFAS means "all substances that include any member of the class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom." This definition has broad impact on nearly every sector of the economy, including Food and Drug Administration (FDA) regulated consumer healthcare products. While little to no OTC product manufacturers intentionally use PFAS in their products, this broad definition runs the risk of including commonly used OTC medicines in the grouping. For example, Flonase (fluticasone), a drug reviewed by the FDA and found to be safe and effective for OTC treatment of symptoms of rhinitis (e.g., sneezing, runny nose, watery eyes), contains a fully fluorinated carbon atom. Under the proposed definition of PFAS in the Second Concept Draft, a product like Flonase – an OTC corticosteroid utilized by millions of allergy sufferers worldwide – would be classified as a PFAS containing product and no longer be eligible for sale in Maine after 2030. To avoid the unintentional inclusion of FDA approved product ingredients in the definition of PFAS, CHPA recommends revising the proposed definition to be consistent with the Toxic Substances Control Act – Section 3(2)(B) which specifically exempts any food, food additive, drug, cosmetic, or device, as defined by the Federal Food, Drug, and Cosmetic Act (FDCA) from the definition of chemical substances. This exemption is restated in a June 2021 proposed rule pertaining to reporting and recordkeeping of PFAS (Fed Reg 86(121) June 28, 2021.

**Establishment of PFAS Ranges**

The Second Concept Draft requires product manufacturers to report the presence of intentionally added PFAS in products beginning January 1, 2023. The requirement includes specifics about PFAS concentration in a product or any product component that falls within an approved DEP range. No guidance, however, is provided to manufacturers on how to establish the DEP approved ranges. While there are established methods for examining the presence of PFAS in the natural environment (air, water, land, etc.), there are inadequate, commercially available methods for the testing of specific PFAS materials in the complex

structures of consumer products. As a result, it is impossible for the consumer healthcare product industry to comply with the reporting requirement as described in the Second Concept Draft without the prior publication of DEP reporting ranges.

**Expansion of Rule to Include PFAS in Packaging**

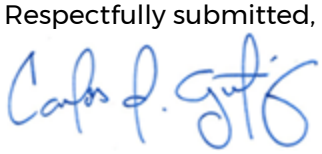
The first concept draft aligned with the original definition of the law as passed by the legislature in that it applied solely to intentionally added PFAS to a product. The Second Concept Draft, however, has been expanded to include product components such as packaging. This expansion of the definition is not only inappropriate due to its inconsistency with the originally adopted law, but such a drastic expansion so close to the compliance date of January 1, 2023 makes it virtually impossible for a product manufacturer to comply with the expanded rule. The consumer healthcare product industry has not had the time to determine the presence of PFAS in its packaging supply chain and identifying such presence could take a significant amount of time. Inclusion of packaging in this draft rule multiplies the amount of testing a manufacturer would need to conduct. Given the increased demand for PFAS testing by all product manufacturers, the availability of testing laboratories may not be sufficient to meet the time frame of the legislation/rule even if a six-month extension is provided to petitioners. Therefore, CHPA strongly recommends reverting back to the original intent of the legislation and applying this PFAS reporting requirement solely to a product sold in the State of Maine and not additional product components.

**Disclosure of Proprietary Information**

The Second Concept Draft's notification section includes a requirement of manufacturers to disclose estimated sales volume of a product that contains intentionally added PFAS. Intellectual assets like sales volume data are proprietary information that are highly sought-after commodities to competitors in a marketplace. Given the sensitivity of this information, it is highly important that this communication be protected from potential abuse or diversion. CHPA recommends the DEP provide explicit assurance that this information will remain confidential and not available for public consumption on platforms such as web sites or other communications tools.

Thank you for the opportunity to comment on this Second Draft Concept. We appreciate your consideration and hope you will incorporate our concerns into your final rule. Please feel free to contact me directly with any questions.

Respectfully submitted,



Carlos I. Gutiérrez
Vice President, State & Local Government Affairs
Consumer Healthcare Products Association
Washington, D.C. | 202.429.3521 | cgutierrez@chpa.org