HALEON

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Stephen Astle, Director
Defense Industrial Base Division, Office of Strategic Industries and Economic Security
Bureau of Industry and Security
Department of Commerce
Docket No. 250414-0065
XRIN 0694-XC120

Dear Mr. Astle:

On behalf of Haleon and the millions of families who use our products, we write to share our recommendations as your agency examines scope and impact of proposed pharmaceutical product inclusion under Section 232 of the Trade Expansion Act of 1962.[1] As a consumer healthcare company, many of the products in our portfolio are regulated by the U.S. Food and Drug Administration ("FDA"). In some instances, our products (and their components) are subject to many of the same regulations as their prescription drug counterparts. For example, just like prescription drugs, many over-the-counter ("OTC") drug products may be marketed only upon FDA approval of a new drug application ("NDA") establishing that the product is safe and effective. However, unlike prescription drugs, OTC drug products may only be marketed if the FDA also agrees that the labeling provides clear usage instructions for treating self-diagnosable, self-treatable acute conditions.

These additional requirements applicable to OTC drug products make us unique in the healthcare space. In our view, the OTC drug portfolio should be viewed carefully and holistically in the context of Section 232 investigations. The potential of a shortage for these products, which are relied upon by children, elderly and adults of all ages for the relief of symptoms associated with a wide range of illnesses and conditions, presents a significant risk to millions of people and public health generally. Impacts on the OTC drug portfolio will be immediately noticeable to consumers at points of sale, as these items are readily available in consumer-satisfaction settings. We recommend interagency consultation and delayed implementation to minimize the risk of shortages for the ingredients found in lawfully marketed OTC drug products. We appreciate your agency granting us the opportunity to express our perspectives while the investigation continues.

About Haleon

Haleon is a leading global consumer healthcare company, holding top positions in several markets, including the United States. We combine science and consumer insights to create innovative everyday healthcare brands that consumers trust and experts recommend for addressing a wide variety of illnesses and health conditions, including oral health, pain relief, cold, flu and allergy,

[1] 19 U.S.C. 1862

smoking cessation, and digestive health. Our everyday brands include Advil, Flonase, Sensodyne, and Tums. We focus on scientific and technical research to create and introduce new products that address consumer needs while aiming to lower the overall impact on the healthcare system. We proudly manufacture across the United States, and our facility locations from Nebraska to Puerto Rico have allowed us to manufacture and streamline our supply chain to serve our American consumers with many products that are manufactured in the United States.

I. Scope

Our comments will focus on recommendations specific to the OTC drug industry, including finished drug products and active pharmaceutical ingredients permitted to be used in these products in accordance with an approved NDA or OTC drug monograph. OTC drugs may be used without a prescriber's authorization, provided they have an acceptable safety margin, low potential for misuse or abuse, and are adequately labeled so that consumers can self-diagnose the condition, self-select the medication, and self-manage the condition.[2] On March 27, 2020, President Trump signed the CARES Act, which modernized the OTC drug monograph rulemaking process with the administrative order process—a less burdensome alternative.[3] In these patient settings, the OTC monograph plays a critical role and sets the conditions under which OTC drug products are generally recognized as safe and effective (GRASE) for their intended use.[4] Compliance under the monograph means that products do not need FDA approval of its NDA prior to marketing.[5] The national portfolio of OTCs play a significant role in public health. According to the Consumer Healthcare Products Association (CHPA), OTCs generate $167.1 billion in savings to the healthcare system by reducing unnecessary healthcare visits and prescriptions.[6]

In addressing the questions posed in the register, we focus on three themes: the projected demand of consumer healthcare products, the capabilities of current supply chains to meet domestic demand, and the previous application of ingredient-specific approaches under Annex II for compliance purposes and its relevance to pharmaceutical applications under section 232 authorities.

II. Projected Demand for Consumer Healthcare and Self-Care Products is Likely to Increase in Light of Recent Executive Orders and Public Health Policy Priorities

According to a 2025 Bank of America Institute analysis, consumer spending on self-care is on the rise across age groups.[7] As American families increasingly seek self-care options to manage their

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[2] U.S. Food and Drug Administration. FDA, "Regulatory Approaches for Prescription to OTC Switch," July 2, 2015, https://www.fda.gov/media/93193/download.
[3] See FFDCA Section 505G.
[4] Congressional Research Service. FDA Regulation of Over-the-Counter (OTC) Drugs: Overview and Issues for Congress. December 10, 2021. https://www.congress.gov/crs-product/R46985
[5] Ibid.
[6] Consumer Healthcare Products Association. The Power of OTCs to Provide Consumer Value. November 2022. https://www.chpa.org/sites/default/files/media/docs/2022-11/The-Power-of-OTCs-to-Provide-Consumer-Value.pdf
[7] Bank of America Institute. Consumer Morsel: There's strength in beauty. January 24, 2025. https://institute.bankofamerica.com/content/dam/economic-insights/consumer-self-care-preferences.pdf

health outside of the hospital system, the demand for accessible and affordable over-the-counter medications is expected to rise. There are data that illustrate this trend: Americans make 26 trips a year to pharmacies and other retailers to purchase OTC products. They only visit doctors, on average, three times a year.[8] In response, we meet Americans at their preferred retailers and pharmacies. Our products on retail shelves are manufactured in America at various facilities across the U.S. and are developed with trusted science and preventative wellness in mind.
As patients across the country depend on these accessible resources, we must look for ways to continue to make them affordable and reliable with a supply chain that can withstand consumer demands in an increasingly evolving environment that is subject to federal and state regulations.

Haleon continues to invest in the U.S. to meet continuously developing market needs. The organization recently announced a $54.2 million investment in Richmond, VA to help meet research and development (R&D) needs for the global market.[9] Based on publicly available data, the global number of OTC sales from 2023 to 2033 is expected to grow by seven percent.[10] We look forward to continue serving increased demands worldwide, and our investment in Richmond is a testament to our approach in leveraging U.S. talent for global innovation.

Our footprint in the U.S. has become increasingly relevant in light of Executive Order 14273, which directs both the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) to undertake a number of actions to reduce prescription drug pricing, including identifying prescription drugs that can be safely provided to patients over the counter.[11] The OTC portfolio has room for growth across pain management, digestive health, and other categories. We support the Administration's approach in making more healthcare products accessible and affordable for patients by removing disproportionate regulatory regimes. Given recent trends in self-care and preventive healthcare awareness, we encourage the agency to consider delayed implementation for OTC drug monograph products. Although most of our products have Active Pharmaceutical Ingredients (APIs), our portfolio depends on a monograph of safe and trusted ingredients that are readily available on store shelves at retailers—not behind the counter at pharmacies. The monograph, as previously noted, establishes conditions, such as active ingredients, uses (indications), doses, routes of administration, labeling, and testing, under which an OTC drug in a given therapeutic category (e.g., sunscreen, antacid) is generally recognized as safe and effective (GRASE) for its intended use without a prescription.[12]

III. Haleon Assessment of Domestic Production of Pharmaceuticals and Active Pharmaceutical Ingredients (APIs)

This projected increase in demand of OTC medications compels our industry to continue its access to pharmaceutical grade ingredients millions of Americans rely on for their everyday care. As a

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[8] Consumer Healthcare Products Association. OTC Sales Statistics. https://www.chpa.org/about-consumer-healthcare/research-data/otc-sales-statistics
[9] Karri Peifer. Axios Richmond. Advil-maker Haleon investing $54.2 million in its Richmond plant. January 28, 2025. https://www.axios.com/local/richmond/2025/01/28/haleon-advil-investing-richmond-plant
[10] https://www.biospace.com/over-the-counter-otc-drugs-market-size-to-hit-us-229-01-billion-by-2033
[11] See Section 9, Executive Order 14273. https://www.federalregister.gov/documents/2025/04/18/2025-06837/lowering-drug-prices-by-once-again-putting-americans-first
[12] U.S. Food and Drug Administration. OTC Drug Review Process | OTC Drug Monographs. https://www.fda.gov/drugs/otc-drug-review-process-otc-drug-monographs

consumer company, we pride ourselves in our legacy in keeping the vast majority of our production close to our markets. In general, 80 percent of what we produce is localized to the region where we operate. However, in a globalized world it is difficult to obtain 100 percent production with current regulatory limitations and consumer preferences. For example, folic acid—an ingredient used in many dietary supplements and deemed necessary for a healthy pregnancy—is primarily produced outside the U.S. While we welcome further opportunities to continue expanding our U.S. sourcing strategy, such expansion is dependent on future anticipated regulations and guidance that would apply to the inspection and approval of new and expanded manufacturing capacity of pharmaceutical products, active pharmaceutical ingredients, key starting materials, and associated raw materials in the United States. We look forward to seeing details as these proposals continue to develop and encourage additional time for commenting periods.[13]

We recommend delaying tariffs on FDA-approved OTC products, as they are essential for pharmacies, retailers, and small businesses. President Trump's actions improving access to these products should remain intact. President Trump's previous actions aimed at improving patient access to OTC products should be preserved under its original intent.[14]

In addition, we emphasize the need for the statutory-based definition to be further supplemented by adding a cross reference to section 9(b) of Executive Order (EO) 14273. This dual-pronged approach and definition provides flexibility for both the HHS and FDA to determine classes of drugs/applications eligible for Rx-to-OTC switch status.[15] These products serve as the first line of defense for millions of Americans and continue to serve a proactive role in reducing costs to safety net programs. We believe that this comprehensive approach fosters the appropriate market conditions for Rx-to-OTC Switch that the Administration pursues as part of its healthcare policies.

Lastly, we do not report any previous instances of unfair trade practices or state-sponsored overproduction for trusted ingredients in the monograph. In our view, the consumer-facing nature of OTC products provides little incentive for price manipulation on one premise alone: consumers simply will not treat minor health issues if OTCs are not affordable. OTC affordability continues to be a critical supporting infrastructure of the healthcare system. The needs of consumers—met in tandem with suppliers, manufacturers, and retailers, serve as a deterrent against price gauging or other unfair trading practices in ordinary daily market conditions.

IV. Previous Approaches on Tariffs and Specific Ingredients Provides a Roadmap for Pharmaceuticals While Generating Clarity for Business Continuity Purposes

On April 2, 2025 President Trump announced the use of reciprocal tariffs to meet U.S. foreign policy and domestic goals. As part of that announcement, the Administration announced a comprehensive package of exempt items under Annex II. Vitamins, A, B1 (thiamine), B2 (riboflavin), B5, B6, B12, C, and E were all included under the published Annex, and provided clarity for business continuity purposes. The strategy was well thought out by the Administration,

[13] See Section 5, Executive Order Regulatory Relief to Promote Domestic Production of Critical Medicines – The White House

[14] See EO 14273, Lowering Drug Prices by Once Again Putting Americans First, Section 9(b)

especially since inputs like Vitamin C do not have enough supply to meet domestic demand in the United States. Paracetamol, Caffeine and Sucralose—for example—have limited supply chain sources for the U.S. market. Each of these items are used in pain medication, migraine relief, and nutritional intake for fiber. Limited supply would likely lead to supply shortages, and expansion of Annex II should be considered as appropriate for OTC products and their respective inputs.

Disruption in the supply chain may cause shortages of critical OTC medications, such as pain relievers, allergy medications, and cold remedies, which are vital for everyday health management. American consumers depend on the shelves of their local retailer to be stocked with these medications for their relief from common ailments and onshoring the production of these ingredients will take time and resources.

We encourage the Administration to provide appropriately timed and delayed implementation in order for companies to search for new suppliers to ensure that consumers see minimal disruption and changes to packaging and appearance of their preferred brands and products.

V. Conclusion

We thank your agency for providing us an opportunity to submit comments reflecting the rapidly changing consumer landscape and the Administration's public policy goals. We look forward to working with the Administration and Congress in a bi-partisan fashion to strike an appropriate balance of consumer healthcare needs for families that use our products to advance their everyday health.

Sincerely,

Jonathan Martinez
Head, U.S. Federal Affairs
Haleon