NATIONAL ASSOCIATION OF Manufacturers

February 2, 2026

The Honorable Martin A. Makary, M.D., M.P.H.
Administrator
Food and Drug Administration
U.S. Department of Health and Human Services
5630 Fishers Lane
Rockville, MD 20857

Re: FDA Docket No. FDA-2025-N-4731: "Increasing Access to Nonprescription Drugs; Request for Information"

Dear Administrator Makary,

The National Association of Manufacturers ("NAM") appreciates the opportunity to submit comments to the Food and Drug Administration ("FDA") in response to the request for information ("RFI") on how to increase access to nonprescription drugs.

The NAM is the largest manufacturing association in the United States, representing small and large manufacturers of every size, in every industrial sector, and in all 50 states. Small and medium-sized manufacturers make up the majority of manufacturing businesses in the United States and employ approximately 40% of the nearly 13 million manufacturing workers. Manufacturing contributes $2.94 trillion annually to the U.S. economy and accounts for nearly 53% of all private-sector research in the nation.

Consumer health care manufacturers are committed to helping people stay healthy and enabling them to make their own health care decisions by making products that help improve people's lives with a simple visit to the pharmacy or grocery store. Also called over-the-counter ("OTC") medicines, nonprescription drugs are a convenient and accessible avenue to help patients treat common illnesses and conditions that do not require a trip to the doctor or guidance from a health care professional. Further, OTC medicines allow individuals to begin treatment immediately—when they need it the most.

Expanding access to nonprescription drugs will help curtail rising health care costs, particularly as the United States experiences a physician shortage. Prescription drugs require doctor's visits, which involve not just the time spent at the appointment itself, but also the time needed to schedule an appointment or locate an in-network provider if a patient does not already have one, as well as the financial cost of a copay or coinsurance. Manufacturing workers taking time off from work to see a doctor reduces workplace productivity at a time when the industry is already facing a manufacturing worker shortage. OTC drugs can help workers to recover more quickly and return to work sooner.

Manufacturers have a longstanding commitment to providing health benefits to their workers as both an effective tool to attract and retain employees and to maintain a healthy and productive workforce. They also believe it is the right thing to do for the workers who keep America and its economy strong. However, rising health care costs remain a top challenge for the industry.

Seventy percent of manufacturers cited health care and insurance costs as their primary business concern in the NAM's most recent Manufacturers' Outlook Survey.[1] Increased costs are disproportionately impacting small and midsize manufacturers, with 77.3% of small (fewer than 50 employees) and 77.6% of medium (50 to 499 employees) companies identifying health care costs as their top concern. Despite this challenge, 95% of manufacturing employees are eligible for health insurance benefits, 80% of whom participate in a workplace plan, which underscores the urgent need for action to reduce health care costs for manufacturers and manufacturing workers alike.[2] Increasing access to nonprescription drugs will help chip away at the high cost of health care burdening manufacturers, their workers, and their families.

Manufacturers commend the Administration for its focus on expanding access to OTC drugs to help lower the cost of health care. Nonprescription drugs save Americans time and money at a moment when rising health care costs are significantly impacting workers and the manufacturers who offer health benefits to them and their families. In addition to policies that help spur innovation in this sector, implementation of the following policy recommendations will support future development and availability of OTC medicines.

I. Challenges faced in the development of drugs for nonprescription use (Question 1).

Excessive and unnecessary regulatory requirements

All drug manufacturers, whether producing prescription or nonprescription medicines, make investment decisions based in part on regulatory certainty. Nonprescription drug manufacturers also consider the likelihood that certain drugs can successfully switch from prescription to OTC. Removing unnecessary burdens in the nonprescription drug regulatory process will create certainty for manufacturers, speeding up switches and increasing access to nonprescription drugs for consumers. For example, some of the evidentiary standards that FDA applies to OTC drugs are more akin to those required of prescription drugs, and application may not make sense for OTC drugs.

Additionally, FDA requires proof that OTC drugs are "safe for self-medication," meaning they must be safe for consumers to take without the supervision of a health care professional. For switch drug applications, where a medication has already been proven safe and effective in a more protective environment, label comprehension and selection studies, among others, are often required to ensure consumers can read the Drug Facts Label on the box, understand the associated risks, and determine if the medicine is the right treatment. Nonprescription drug manufacturers are committed to making safe and effective drugs and seek to get clear alignment with FDA early in the development process on the types of data required and the thresholds that must be met. A smoother and more certain pathway would lead to increased and faster switch approvals and speed up the delivery of innovative, affordable OTC medicines to consumers, allowing them to make better health care decisions.

[1] National Association of Manufacturers, Q4 2025 Manufacturers' Outlook Survey (December 17, 2025). Available at https://nam.org/wp-content/uploads/securepdfs/2025/12/NAM_Q4_2025_Outlook_Write_Up.pdf.
[2] Kaiser Family Foundation, *2025 Employer Health Benefits Survey* (Oct. 22, 2025). Available at https://files.kff.org/attachment/Employer-Health-Benefits-Survey-2025-Annual-Survey.pdf

Tariffs and trade restrictions

Some critical inputs needed to manufacture nonprescription drugs are not currently produced domestically. Tariffs on pharmaceutical inputs can increase production costs for U.S. manufacturers, risk supply chain disruptions, and contribute to escalating costs and shortage risks for U.S. patients. The NAM submitted a comment letter responding to the Department of Commerce's Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients, which argued that immediate and broad-based tariffs on imports of pharmaceutical inputs and finished products, many of which are sourced from allies and through related party transactions, undermines that very supply chain network. That not only harms our global advantage—it also imposes severe and preventable costs at home, particularly the risk that undermining the supply chain network will in turn drive health care costs for American patients while causing shortages for American consumers.

One specific example is the domestic production of ibuprofen, a widely used OTC treatment. The one remaining producer of the API for ibuprofen in the Western Hemisphere, which supplies both the U.S. and European markets and competes against tariff-free imports from China and India, requires an input (isobutyl benzene) that no company currently produces in the U.S. Isobutyl benzene must be sourced from India and is currently subjected to a 50% tariff. This places the sole domestic producer of the API for ibuprofen at a competitive disadvantage against these international competitors. In turn, there is the potential to inadvertently create a supply chain dependency on non-U.S. manufactured ibuprofen. Should there be a worldwide shortage, Americans who rely on ibuprofen would be at the mercy of foreign countries.

Manufacturers appreciate the Administration's commitment to domestic manufacturing, and we support efforts to bolster our domestic supply chain, strengthen the economy, and employ American workers. It is vital that this commitment be paired with policies that enable manufacturers to access the inputs they need to make things here in America.

II. The biggest opportunities to improve access to nonprescription drugs (Question 2).

Updates to the current regulatory framework

- **Broadening the risk/benefit assessment for nonprescription drugs to include the consideration of benefits beyond those to the individual patient in either approval pathway would greatly benefit consumers in the U.S.** FDA should consider the benefits to population health and the health care system overall, the U.S. economy, and monetary savings to federal health care programs, when reviewing OTC drug applications. FDA should update its current risk/benefit framework to ensure appropriate weight and context are assigned to the broader benefits an OTC medicine may have.

- **Manufacturers recommend FDA broaden its consideration of what drugs can be switched from prescription to nonprescription.** The rapidly changing technological landscape and incredible innovation in the biopharmaceutical industry makes drugs that had not previously been considered for a switch potential candidates. The rapid advancement of OTC diagnostics and wearables may even enable new categories of drugs to be switched. As such, FDA should expand its viewpoints about which drugs can be switched, dedicate resources to proactively consider switches, and encourage regular consultation with biopharmaceutical companies on plans to remove the prescription-only requirement.

- **FDA should appropriately value innovation in the development of nonprescription drugs.** Biopharmaceutical companies are incredibly innovative, with the primary goal of improving people's health. Advisory councils should include individuals, including health care professionals and patient advocates, that can speak to the importance of innovation. Health care professionals with relevant and specialized experience can appropriately consider how certain innovative medications would benefit certain populations. Advisory councils are currently the only opportunities for patient advocates with incredibly valuable expertise to weigh in on potential switches from prescription to OTC and best explain the real-world benefits and impacts of a switch. Manufacturers recommend FDA ensure specialized health care professionals and patient advocates be consistently included on advisory councils and consider the positions their expertise leads them to take.

- **The NAM has long advocated for the federal government to rebalance regulations and reduce unnecessary burdens that impede growth across the manufacturing sector.** Clear, predictable, and right-sized regulatory processes are essential for manufacturers to sustain the significant financial investment required for prescription-to-OTC switches. FDA must continue to engage with key stakeholders, including industry, to identify overreaching and excessive regulations that would benefit from thoughtful rebalancing. Doing so will help manufacturers continue to develop innovative OTC medicines that meaningfully impact people's lives.

- **FDA should maintain its incentive for certain OTC drug switches that require significant financial investment.** Switching a prescription drug to OTC requires manufacturers to prove, sometimes through expensive clinical trials, that a product can be used safely without physician supervision for some or all approved indications. When such trials are needed for approval, FDA appropriately incentivizes manufacturers to apply for the switch and conduct the trials with the promise of three years of exclusivity. Manufacturers encourage FDA to maintain this important incentive, which supports manufacturer investment and innovation.

III. Working together to increase access to safe and effective nonprescription drugs (Question 3).

Americans in underserved areas, such as health care deserts where there is inadequate or no access to medical services, would greatly benefit from increased access to nonprescription drugs. Sick people who may be unable to see a doctor, perhaps because there is a physician shortage where they live or work, may then also be unable to get the medicine they need, leading to a sicker population in need of increased medical services. The more OTC medicines available, the better health outcomes we may expect to see in these populations.

Collaboration between FDA, OTC drug manufacturers, and health care providers to increase the amount of approved and available nonprescription drugs will further help those living in health care deserts by expanding the available OTC drugs they can purchase. Regular, proactive consultation between FDA and biopharmaceutical companies is essential to enable increased accessibility of OTC medications. Manufacturers encourage the agency to explore additional avenues, such as regular in-person engagement, to work with OTC manufacturers to help meet the needs of Americans in underserved areas.

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Increased access to nonprescription drugs is crucial for manufacturers as providers of employer-sponsored insurance, and for manufacturers of consumer health care products, who strive every day to improve the health and lives of Americans. The NAM appreciates FDA's consideration of these comments, and manufacturers look forward to working together to increase access to OTC medications.

Sincerely,

Jess Wysocky
Director, Health Care Policy

Jake Kuhns
Vice President, Domestic Policy