Asthma and Allergy Foundation of America

July 6, 2026

The Honorable Kyle Diamantas
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue Silver Spring, MD
20993

Re: Metered-dose inhalers (pMDIs) to Manage Chronic Respiratory Disease

Dear Acting Commissioner Diamantas:

On behalf of the Asthma and Allergy Foundation of America (AAFA), I am writing to share our perspective on an issue of significant importance to the millions of people in the United States who rely on pressurized metered-dose inhalers (pMDIs) to manage chronic respiratory disease.

AAFA is the leading patient organization for people with asthma and allergies and the oldest asthma and allergy patient group in the world. We are dedicated to improving the quality of life for people with allergic diseases and asthma through education, support, advocacy and research. Asthma is one of the most common and costly diseases in the U.S., affecting nearly 28 million Americans, including about 5 million children. The total economic cost of asthma in the United States was about $82 billion per year from 2008 to 2013, or $118 billion in CPI adjusted dollars in 2026. Without prevention and effective management, costs will rise—especially for emergency care and hospitalizations.

Manufacturers are transitioning pMDIs from hydrofluoroalkane (HFA) propellants to lower–global-warming hydrofluoroolefin (HFO) propellants. While we understand the environmental and regulatory imperatives driving this shift and support efforts to reduce the climate impact of essential respiratory therapies, we are concerned about the unintended consequences that may create barriers for patients to receive their asthma medication without unnecessary gaps, especially based on past history.

When manufacturers moved from chlorofluorocarbon (CFC) propellants to HFAs under the Montreal Protocol, the transition produced measurable disruption in how patients used and accessed rescue medication. FDA required full New Drug Applications for each reformulated product. Generic albuterol inhalers were pulled from shelves and replaced only by branded, higher-cost HFA products. A peer-reviewed study of children with asthma enrolled in four health maintenance organizations documented this disruption among children whose copayments rose after losing generic access.[1]

From the patient perspective, the regulatory pathway used to review new HFO products could have real implications for continuity of care. A new drug application (NDA) approach would mean that the HFO version of a drug would have a different national drug code, or NDC, from the HFA version. Under a new NDA, the HFO version gets a different NDC and is treated by payers as a new drug product — subject to fresh formulary, tier, and coverage review. Because pharmacies cannot automatically substitute a product with a different NDC, patients, including those with active refills, would need a new prescription for the HFO version.

This distinction matters even during the transition period when both HFA and HFO versions are on the market. Manufacturers are expected to introduce HFO products on a rolling basis while HFA versions remain available.[2] If HFO inhalers enter the market under new NDCs, payers will treat them as new drug products subject to their standard formulary review processes. Research on Medicare Part D coverage of newly approved drugs found that newly approved drugs in nonprotected classes are frequently subject to formulary exclusions and coverage restrictions including prior authorization and step therapy requirements in the period immediately following approval.[3] For patients whose HFA inhaler is covered today, an HFO version with a new NDC may not be covered on the same terms — or at all — without a separate coverage determination. The practical result is that patients attempting to transition to the HFO version of their existing medication could face delays, additional administrative steps, or higher out-of-pocket costs, even while the HFA version remains technically available.

For many patients, especially those managing chronic respiratory disease, this additional step introduces risk. Delays in reaching a prescriber, gaps of several days without controller therapy, or deferring treatment until a future appointment can all contribute to treatment interruptions. These interruptions are associated with increased risk of exacerbations, urgent care visits, hospitalizations, and, in severe cases, life-threatening outcomes. We are particularly concerned about the potential for therapy abandonment among patients who already face significant barriers to adherence. Given the number of rescue and maintenance inhalers affected, the cumulative impact across a population of 28 million patients with asthma could be substantial.

Maintaining two NDCs for clinically equivalent products also increases administrative burden across the care continuum. Prescribers, pharmacies, payers, and patients would all face added complexity, raising the likelihood of dispensing errors and confusion. The precedent set here could amplify disruption across multiple rescue and maintenance inhalers.

AAFA believes that the Prior Approval Supplement pathway would avoid creating a new, separate NDC for a clinically equivalent reformulation. This would better safeguard continuity of care and reduce risks for patients and clinicians. Using a comparable approach for future generics would also facilitate the availability of affordable alternatives when patent protections expire.

Of course, it is of the utmost importance that FDA have the data to confirm that the PAS pathway would provide safety, efficacy, and quality for this category of product transitions. As FDA considers the approach, we encourage the agency to incorporate input from patient and nonprofit partners who can speak directly to the realities of adherence, access, and care continuity. AAFA welcomes the opportunity to share additional insights with the FDA.

Thank you for your attention to this issue and for your continued commitment to protecting patients during this important transition.

Sincerely,

Kenneth Mendez
President and Chief Executive Officer
Asthma and Allergy Foundation of America

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[1] Galbraith AA, Fung V, Li L, et al. Impact of Copayment Changes on Children's Albuterol Inhaler Use and Costs after the Clean Air Act Chlorofluorocarbon Ban. *Health Services Research*. 2018;53(1):156-174. https://doi.org/10.1111/1475-6773.12615

[2] AstraZeneca has committed to completing its HFO propellant transition by 2030, with products launching on a rolling basis beginning in 2025, indicating a multi-year coexistence period for HFA and HFO versions of the same products. AstraZeneca. Transitioning our pMDIs with reduced climate impact. Available at: https://www.astrazeneca.com/media-centre/articles/2025/advancing-sustainable-respiratory-care-with-the-transition-to-pMDIs-with-near-zero-GWP-propellant.html

[3] Salazar EY, Dusetzina SB, et al. Coverage of New Drugs in Medicare Part D. Health Affairs. 2022. https://pmc.ncbi.nlm.nih.gov/articles/PMC9205672/ (Finding that only a small minority of newly approved drugs in nonprotected classes are widely covered by Part D plans in the year after FDA approval, and that prior authorization and step therapy requirements are frequently applied.)