American Lung Association.

February 2, 2026

Martin A. Makary, M.D., M.P.H.
Food and Drug Administration
White Oak Campus
10903 New Hampshire Ave
Silver Spring, MD 20993

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

Dear Commissioner Makary:

The American Lung Association appreciate the opportunity to provide comment on *Increasing Access to Nonprescription Drugs.*

The American Lung Association is the oldest voluntary public health organization in the United States. One of our four strategic imperatives is to create a tobacco-free future, and tobacco cessation is vital to that effort. The Lung Association believes that everyone who uses and is addicted to commercial tobacco products[1] can quit, not just switch to another tobacco product. There are currently seven medications approved by the Food and Drug Administration (FDA) for smoking cessation, three of which are nonprescription drugs. Helping people quit their addiction to tobacco is both integral to our mission and is of the upmost national importance. Tobacco use is the leading cause of preventable death and disease in the United States, responsible for the deaths of 490,000 people in the U.S. annually.[1] An additional 16 million people in the U.S. live with a disease caused by tobacco.[2]

The Lung Association encourages FDA to focus on tobacco cessation treatment and include it as part of its work to increase access to nonprescription drugs. In 2024, FDA along with the National Institutes of Health (NIH), held a meeting and subsequently asked for information on Advancing Smoking Cessation. This work is vital to improving the lives and health of all Americans and we urge FDA to continue to work to encourage more tobacco cessation treatments, including non-prescription drugs.

FDA can create a regulatory environment and pathway that encourages and facilitates responsible companies' efforts to produce and market new and more effective tobacco cessation products, including non-prescription drugs. The last new cessation product that received an FDA approval was in 2006 - 20 years ago. During this time period, novel tobacco products, including e-cigarettes and pouches, have emerged onto the market, addicting new generations to tobacco, setting them up for a lifetime of addiction and disease.

FDA should review its processes, including an assessment of barriers that reputable companies face when pursuing the Center for Drug Evaluation and Research (CDER) pathway to bring a drug to market. After the review of barriers, FDA should look for ways to ameliorate them.

[1]References to tobacco refer to commercial tobacco and not the sacred and traditional tobacco that may be used for ceremonial or medicinal purposes by some American Indian communities.

FDA should take affirmative steps to explore alternatives to long-term clinical trials for promising new cessation products or for new indications for existing cessation products where sufficient evidence is available to meet both safety and efficacy. Examples of this are adding an indication for tobacco cessation products, like nicotine replacement therapy (NRT), to reduce the number of cigarettes smoked each day as part of a "reduce to quit" regime.[3] This can be a point on the path in a person's quit journey and help them quit tobacco for good. Another example of this would be changing the labeling of NRT for combination therapy. This is when a patient is prescribed both short and long acting NRT. For patients that have a very severe tobacco addiction, combination therapy can help them be successful in quitting.[4] Both short and long acting NRT are available as non-prescription medications. This labeling change could make these medications more effective for people who are severely addicted to tobacco.

Non-prescription drugs are an important tool to help people who smoke quit for good. Encouraging the development and approval of more cessation treatments, including non-prescription drugs, will help reduce the burden of tobacco cause disease and death and create a healthier country. The Lung Association urges FDA to include cessation drugs as part of their work on Increasing Access to Nonprescription Drugs.

Sincerely,

Deborah Brown
Chief Mission Office

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[1] U.S. Department of Health and Human Services. Eliminating Tobacco-Related Disease and Death: Addressing Disparities—A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2024.

[2] U.S. Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014.

[3] Hartmann-Boyce J, Chepkin SC, Ye W, Bullen C, Lancaster T. Nicotine replacement therapy versus control for smoking cessation. Cochrane Database Syst Rev. 2018 May 31;5(5):CD000146. doi: 10.1002/14651858.CD000146.pub5. PMID: 29852054; PMCID: PMC6353172.

[4] Ebbert JO, Hays JT, Hurt RD. Combination pharmacotherapy for stopping smoking: what advantages does it offer? Drugs. 2010 Apr 16;70(6):643-50. doi: 10.2165/11536100-000000000-00000. PMID: 20394453; PMCID: PMC3164516.