# Supporting Novel Nicotine Replacement Therapies to Help Smokers Quit

The draft guidance will outline ways to develop and label smoking-cessation aids to reduce the risk of relapse.

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Statement from FDA Commissioner Scott Gottlieb, MD, on additional steps by the agency to support the development of safe and effective novel nicotine replacement therapies to help smokers quit cigarettes

More than 54 years after the landmark Surgeon General's report on smoking and health, tobacco use – primarily cigarette smoking – remains the leading cause of preventable disease and death in the U.S., responsible for 480,000 premature deaths each year. Why? Because cigarettes are incredibly addictive.

Most adult smokers want to quit, and nearly half try to do so every year. But nicotine, which a cigarette efficiently delivers through the lungs and to the brain in less than 10 seconds, draws many people back despite their desire to stop.

While nicotine keeps smokers addicted, it's the smoke and the 7,000 chemicals contained in it that causes the disease and death. That's why a key element of our comprehensive plan to significantly reduce tobacco-related disease and death is recognizing that nicotine, while highly addictive, is delivered through products along a continuum of risk with combustible cigarettes at one end, and nicotine replacement therapy (NRT) products at the other. In particular, NRT products, which are designed to safely reduce withdrawal symptoms, including the nicotine craving associated with quitting smoking, are generally considered to double the likelihood of a successful quit attempt. Quitting smoking can lower a person's chances of having lung disease, heart disease or getting certain types of cancer.

Most existing NRTs such as gums, patches and lozenges have been approved for more than 30 years. They have played an important role in providing adults with tools to help quit smoking, in a manner that doesn't require cutting themselves off immediately and entirely from nicotine. Now, we have an opportunity to build on these NRTs, with novel products that may provide an opportunity to save even more lives by empowering adults to safely and effectively quit smoking.

Novel products with different characteristics or routes of nicotine delivery have the potential to offer additional opportunities for health-concerned smokers interested in quitting. This could also include products such as electronic nicotine delivery systems like electronic cigarettes, but which would need to be proven safe and effective for smoking cessation and regulated as a drug product. This would allow them to be marketed as a prescription or over-the-counter drug products with medical claims for smoking cessation or related indications – ultimately reducing the likelihood of someone continuing to suffer the clinical consequences of smoking. This is different from our regulation of e-cigarettes as tobacco products.

As part of our commitment to increasing access and use of FDA-approved medicinal nicotine products, we established the Nicotine Steering Committee in September 2017. Since then, the committee has been focused on creating a more flexible framework that enables the development of safe and effective product innovations that have the potential to help smokers quit combustible cigarettes and improve their health. This included holding a public hearing in January 2018 examining the types of safety and efficacy studies we suggest be conducted and the way these products are used and labeled and developing guidance to facilitate the development of these products.

Building on these efforts to encourage innovation of drug products to help more smokers quit cigarettes, today, we're releasing the second of two draft guidances aimed at supporting the development of novel nicotine replacement therapies that could be sold as new FDA-approved drugs, similar to current prescription and over-the-counter NRT drug products.

The first guidance released in August 2018, "Nonclinical Testing of Orally Inhaled Nicotine-Containing Drug Products," focused on data recommended to evaluate potential toxicities associated with orally inhaled nicotine-containing drug products (such as e-cigarettes) to inform the FDA's assessment of a product's benefits and risks. That draft guidance recognizes that a great deal of toxicity information is available for nicotine, but such information may not be available for other compounds like flavorings and heat-generated chemicals contained in e-liquids and delivered by these products. Because these products can be used for six months or more over the course of a lifetime, it's important to understand the risks to humans from these exposures, including developmental and reproductive toxicity and carcinogenicity.

The draft guidance issued today, "Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy Drug Products," helps lay out a framework for new potential clinically relevant outcomes for smoking cessation products, such as reducing the chance of a smoker going back to using cigarettes long term. This draft guidance takes into consideration the input received at the public hearing in January 2018 and is intended to serve as a focus for continued discussions among the FDA, pharmaceutical sponsors, the cessation research community, and the public.

The aim of the guidance is to describe new endpoints that are meaningful to helping currently addicted adult smokers, and that can promote innovation in NRT by outlining a broader set of criteria that can serve as the basis for new approvals.

The current labeling for NRT products recommends that the smoker establish a “quit day” and stop smoking cigarettes that day. While this can work for highly motivated smokers, many such quit attempts fail and result in a return to smoking. However, other treatment regimens, such as pre-treatment before quit day, quitting by gradually reducing the number of cigarettes smoked (reduce-to-quit), or using two NRT drug products together, can be explored to help cigarette smokers quit. While NRT drug products to date have been developed for smoking cessation, the draft guidance, when finalized, will outline ways sponsors may develop products to reduce the risk of relapse. Additionally, it will outline ways sponsors may also be able to support including additional information in labeling, such as a reduction of urge to smoke and relief of cue-induced craving in former smokers, or relief of withdrawal symptoms not associated with a cessation attempt.

As we look toward the future and the possibility of a world where combustible cigarettes could no longer create or sustain addiction, these guidances are part of comprehensive steps to pave the way for new, safe and effective products that can help currently addicted smokers quit the deadliest form of nicotine delivery.

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