

VLN Commercial Launches Confirm Viability of the FDA's Proposed Reduced Nicotine Mandate

Jul 16, 2025

Multiple Tobacco Brands Partnering with 22nd Century to Expand Availability and Awareness of VLN Based Reduced Nicotine Content Products

Manufactured in the USA, VLN Products from 22nd Century Provide Clinically Proven Solution to Reduce the Rate and Harms of Smoking

MOCKSVILLE, N.C., July 16, 2025 (GLOBE NEWSWIRE) -- 22nd Century Group, Inc. (Nasdaq: XXII), the only tobacco products company that has for 27 years led and continues to lead the fight against the harms of smoking driven by nicotine addiction is creating a new pathway to reducing the rate of smoking and related health harms through increasing adoption of its VLN[®] reduced nicotine content cigarette products by additional brands. Our products incorporate proprietary and patented tobacco having 95% less nicotine than tobacco used in highly addictive conventional cigarettes. Decades of peer reviewed studies have shown that the level of nicotine content in 22nd Century's products can reduce both the rate of smoking and the health harms of smoking.

The recently announced partner VLN[®] initiatives, such as Smoker Friendly VLN[®], Pinnacle VLN[®], reflect a growing commitment by tobacco brands to accelerate compliance with the U.S. Food and Drug Administration's proposed new [Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products](#), which is intended to curb the harms of smoking.

"The FDA recognizes that nicotine is a highly addictive substance and that to achieve true tobacco harm reduction, nicotine consumption must be addressed. The FDA's new product standard proposed in January is one of many factors that are driving early commercial interest in our VLN reduced nicotine content tobacco products. We are excited to see our customer's brands adding VLN cigarettes to their lineup. This will enhance market availability of VLN cigarettes and offer customers a Tobacco Harm Reduction product that will give the smoker a choice to control their nicotine consumption," said Larry Firestone, Chief Executive Officer of 22nd Century Group. "These commercial launches and our readiness once we receive state approval to scale availability to all 50 states for the entire U.S. cigarette market continues to demonstrate that there need not be any commercial barriers to adopting this FDA policy, which could be the most impactful health decision in a generation."

Formally announced in January 2025, the proposed standard sets a maximum nicotine content of 0.7 mg of nicotine per gram of tobacco in cigarettes and certain other combusted tobacco products, taking effect two years from final approval. VLN[®] based products from 22nd Century are the **only** combustible cigarette products authorized by the FDA to meet the standard, at an average of 0.5 mg per gram, and the only product that offers consumers a choice about their nicotine consumption.

On implementation of the FDA proposal, people who are addicted and wish to alter their dependency or even quit could have the ability to do so more easily, significantly reducing the morbidity and mortality caused by smoking. Based on FDA's population health model, by the year 2100, in the United States, approximately 48 million youth and young adults who would have otherwise initiated smoking would not start as a result of the proposed product standard.

22nd Century is monitoring comment submissions under the proposed rule and intends to make its own submission before the comment period closes.

This activity follows the 2018 rule making process, which ultimately incorporated many of the suggestions, independent clinical research studies and feasibility data from [22nd Century's comment letter at that time](#), including:

- A proposed standard of not more than 0.7mg/g of nicotine content, based on 22nd Century's recommendation of an average of 0.5mg/g,
- The fact that our patented low nicotine content tobacco leaf contained in our VLN Products that already meets the standard can be readily sourced in enough quantity to meet demand for reduced nicotine content cigarette products, and
- The fact the reduced nicotine content tobacco is an effective way to reduce the rate and harms of smoking, as documented by dozens of peer reviewed and published independent clinical studies using research cigarettes manufactured by 22nd Century

The [FDA's January 15, 2025 press release](#) announcing the rule includes the following statement from the former FDA Commissioner Robert M. Califf, M.D.: "Today's proposal envisions a future where it would be less likely for young people to use cigarettes and more individuals who currently smoke could quit or switch to less harmful products. This action, if finalized, could save many lives and dramatically reduce the burden of severe illness and disability, while also saving huge amounts of money. I hope we can all agree that significantly reducing the leading cause of preventable death and disease in the U.S. is an admirable goal we should all work toward."

About 22nd Century Group, Inc.

22nd Century Group is the pioneering nicotine harm reduction company in the tobacco industry enabling smokers to take control of their nicotine consumption.

We created our flagship product, the VLN[®] cigarette, to give traditional cigarette smokers an authentic and familiar alternative that helps them take control of their nicotine consumption. VLN[®] cigarettes have 95% less nicotine than the traditional cigarette and have been proven to allow consumers to greatly reduce their nicotine consumption. Instead of offering new ways of delivering nicotine to addicted smokers, we offer smokers the option to take control of their nicotine consumption and make informed and more productive choices, including the choice to avoid addictive levels of nicotine altogether.

Our proprietary reduced nicotine tobacco blends are made possible by comprehensive and patented technologies and tobacco plants that regulate nicotine biosynthesis activities in the tobacco plant, resulting in full flavor and high yield with 95% less nicotine. Our extensive patent portfolio has been developed to ensure we have the only low nicotine combustible cigarette in the United States and critical international markets.

VLN[®] is a registered trademark of 22nd Century Limited LLC.

Learn more at [xxiicentury.com](#), on [X \(formerly Twitter\)](#), on [LinkedIn](#), and on [YouTube](#).

Learn more about VLN[®] at [tryvln.com](#).

Cautionary Note Regarding Forward-Looking Statements

Except for historical information, all of the statements, expectations, and assumptions contained in this press release are forward-looking statements, including but not limited to our full year business outlook. Forward-looking statements typically contain terms such as "anticipate," "believe," "consider," "continue," "could," "estimate," "expect," "explore," "foresee," "goal," "guidance," "intend," "likely," "may," "plan," "potential," "predict," "preliminary," "probable," "project,"

"promising," "seek," "should," "will," "would," and similar expressions. Forward-looking statements include, but are not limited to, statements regarding (i) our cost reduction initiatives, (ii) our expectations regarding regulatory enforcement, including our ability to receive an exemption from new regulations, (iii) our financial and operating performance and (iv) our expectations for our business interruption insurance claim. Actual results might differ materially from those explicit or implicit in forward-looking statements. Important factors that could cause actual results to differ materially are set forth in "Risk Factors" in the Company's Annual Report on Form 10-K filed on March 20, 2025, and in the Company's Quarterly Reports filed on May 13, 2025. All information provided in this release is as of the date hereof, and the Company assumes no obligation to and does not intend to update these forward-looking statements, except as required by law.

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