



April 25, 2018

## 22nd Century Committed to Advancing FDA's Nicotine Mandate

*Altria and Reynolds American petition FDA for 90-day delay in comment period for proposed nicotine reduction rule*

CLARENCE, N.Y.--(BUSINESS WIRE)-- 22nd Century Group, Inc. (NYSE American: [XXII](#)), a plant biotechnology company focused on tobacco harm reduction and Very Low Nicotine tobacco, announced today that the Company is committed to working collaboratively with the U.S. Food and Drug Administration (FDA) on the FDA's planned nicotine reduction mandate despite the fact that, last week, [regulations.gov](#) published requests from Altria Group, Inc. ([MO](#)) and Reynolds American Inc., a subsidiary of British American Tobacco ([BTI](#)), petitioning the FDA for an additional 90-days beyond the original public comment period that is currently set to end on June 14, 2018.

22nd Century has publicly stated that since it is universally accepted that nicotine is the primary addictive component of cigarettes, the tobacco industry and public health officials must logically support the FDA's plan to mandate that all cigarettes sold in the United States contain only "minimally or non-addictive" levels of nicotine. FDA Commissioner Dr. Scott Gottlieb has built a strong case for this bold policy: "...we'll solve the tobacco crisis by addressing the root issue of tobacco addiction: nicotine.... [We] could save millions of lives."

As investors have begun to realize that the FDA is, in fact, truly committed to its nicotine reduction plan, the share prices for Altria Group, Philip Morris International ([PM](#)), and British American Tobacco all continue to fall and are substantially lower today than they were last June before the FDA's nicotine reduction plan was publicly announced in July 2017.

Nevertheless, misconceptions continue to abound regarding the definition of "Very Low Nicotine;" i.e. tobacco with nicotine **content** at minimally or non-addictive levels. Many American smokers erroneously believe that Big Tobacco companies already offer Very Low Nicotine content brand styles. This simply is not true. National tobacco brands that advertised "low nicotine" or "light" styles in the past were referring to the smoking machine-measured nicotine **yield** of cigarettes. The FDA, the Federal Trade Commission (FTC), and the public health community at large have determined that the **yield** method of nicotine measurement is wholly unreliable and gives no indication of actual nicotine intake because smokers engage in "compensatory behavior" when using low **yield** products and do not actually achieve reduced nicotine intake. For precisely this reason, the FDA banned the terms "light" and "ultra-light" from being used with respect to combustible cigarettes so that tobacco companies could not mislead consumers with these terms.

A better measurement, and one that is advanced in the FDA's Advance Notice of Proposed Rulemaking (ANPRM) to lower dramatically the nicotine level in cigarettes, is the measurement of nicotine **content**. The nicotine **content** of a cigarette cannot be modified by smoking behavior.

22nd Century produces proprietary Very Low Nicotine **content** tobacco cigarettes. 22nd Century's Very Low Nicotine **content** cigarettes have nicotine contents as low as 0.4mg per gram of tobacco. In contrast, even other manufacturers' previously so-called "light" or "ultra-light" cigarettes have nicotine contents 20-30 times higher at 10-15mg per gram of tobacco.

[Dr. Neal Benowitz](#), a tobacco science expert and a professor at the University of California, San Francisco School of Medicine, wrote an article published on August 15, 2017 in the *Annals of Internal Medicine* entitled "[Comprehensive Nicotine Regulation to End the Combustible Tobacco Epidemic](#)." In the perspective article, Dr. Benowitz states that an FDA-mandated 95% reduction in nicotine **content** would "make it impossible to compensate by smoking cigarettes more intensively or smoking more per day." Like many other health experts, Dr. Benowitz recognizes that compensatory smoking does not occur when the nicotine content of combustible cigarettes is reduced by 95% as compared to conventional cigarettes.

22nd Century is the only company in the world that has grown commercial crops of proprietary tobacco with

nicotine levels of just 0.4mg per gram of tobacco – a 95% reduction in nicotine. Independent clinical trials using 22nd Century's proprietary SPECTRUM research cigarettes have shown that Very Low Nicotine content cigarettes **reduce cravings, reduce consumption of cigarettes, and increase quit attempts**. In fact, the research done with 22nd Century's SPECTRUM cigarettes provided the foundation for the FDA's plan to mandate that all cigarettes sold in the United States contain only "minimally or non-addictive" levels of nicotine.

"It now seems clear that Big Tobacco companies are not willing – or able – to comply with the FDA's bold nicotine reduction plan, despite their prior public statements to the contrary," explained Henry Sicignano III, President and Chief Executive Officer of 22nd Century Group. "On the other hand, 22nd Century continues to grow proprietary Very Low Nicotine tobacco with 95% less nicotine. And, in order to save countless lives and in order to prevent millions of young people from becoming addicted to cigarettes, 22nd Century is 100% committed to working collaboratively with any and all tobacco companies that **truly** wish to address the root issue of tobacco addiction."

#### **About 22nd Century Group, Inc.**

22nd Century is a plant biotechnology company focused on technology which allows the Company to increase or decrease the level of nicotine in tobacco plants and the level of cannabinoids in hemp/cannabis plants through genetic engineering and plant breeding. The Company's primary mission in tobacco is to reduce the harm caused by smoking. The Company's primary mission in hemp/cannabis is to develop proprietary hemp strains for important new medicines and agricultural crops. Visit [www.xxiicentury.com](http://www.xxiicentury.com) and [www.botanicalgenetics.com](http://www.botanicalgenetics.com) for more information.

*Cautionary Note Regarding Forward-Looking Statements: This press release contains forward-looking information, including all statements that are not statements of historical fact regarding the intent, belief or current expectations of 22nd Century Group, Inc., its directors or its officers with respect to the contents of this press release, including but not limited to our future revenue expectations. The words "may," "would," "will," "expect," "estimate," "anticipate," "believe," "intend" and similar expressions and variations thereof are intended to identify forward-looking statements. We cannot guarantee future results, levels of activity or performance. You should not place undue reliance on these forward-looking statements, which speak only as of the date that they were made. These cautionary statements should be considered with any written or oral forward-looking statements that we may issue in the future. Except as required by applicable law, including the securities laws of the United States, we do not intend to update any of the forward-looking statements to conform these statements to reflect actual results, later events or circumstances, or to reflect the occurrence of unanticipated events. You should carefully review and consider the various disclosures made by us in our annual report on Form 10-K for the fiscal year ended December 31, 2017, filed on March 7, 2018, including the section entitled "Risk Factors," and our other reports filed with the U.S. Securities and Exchange Commission which attempt to advise interested parties of the risks and factors that may affect our business, financial condition, results of operation and cash flows. If one or more of these risks or uncertainties materialize, or if the underlying assumptions prove incorrect, our actual results may vary materially from those expected or projected.*

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