



The Consumer Advocates for Smoke-free Alternatives Association

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To: U.S. Food and Drug Administration

From: Alex Clark

Executive Director

The Consumer Advocates for Smoke-free Alternatives Association (CASAA)

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Re: CASAA's comments on 22nd Century's "Modified Risk Tobacco Product Applications for VLN™ King and VLN™ Menthol King, Combusted, Filtered Cigarettes, Submitted by 22nd Century Group Inc.," Docket No. FDA-2019-N-0994.

This comment on Docket No. FDA-2019-N-0994, "Modified Risk Tobacco Product Applications for VLN™ King and VLN™ Menthol King, Combusted, Filtered Cigarettes, Submitted by 22nd Century Group Inc.," is submitted on behalf of The Consumer Advocates for Smoke-free Alternatives Association (CASAA). CASAA is a 501(c)(4) nonprofit public health and education organization and is the leading representative of consumers who use--or may in the future choose to use--low-risk, smoke-free alternatives to combustible tobacco. CASAA is a U.S. membership organization with an all-volunteer Board of Directors and a grassroots membership of more than 250,000 members. CASAA is not a trade association and does not represent the interests of industry. CASAA represents consumers and is dedicated to ensuring the availability of a wide variety of reduced harm alternatives to smoking and that people who smoke and non-smokers alike receive honest information about those alternatives so that they can make informed choices.

XXII Century is seeking approval to make the following marketing claim regarding exposure modification for their VLN™ cigarettes:

- "95% less nicotine; Helps reduce your nicotine consumption."

This claim is accompanied by a warning and balancing statement that

- "Nicotine is addictive. Less nicotine does **NOT** mean safer. All cigarettes can cause disease and death."

The claim for which XXII Century is seeking permission to make is inappropriate and will not promote the public health. While CASAA does not object to disclosure of the fact that VLN™ Cigarettes contain a low amount of nicotine, XXII Century is going beyond stating a fact about

an ingredient to claiming that these cigarettes can help reduce nicotine *consumption*. Such a claim suggests that these combustible products may be used as a part of a smoking cessation strategy or therapy. This is beyond the scope of any reduced exposure claim that might be proposed by any manufacturer not seeking approval for a therapeutic drug or device.

Moreover, while CASAA is not opposed to accurately disclosing nicotine content in cigarettes by way of including this information on individual packs, we are concerned that consumers have not been properly informed about the difference between exposure and risk. There is significant possibility for confusion among consumers that the reduced exposure claim will be equated with reduced risk. While XXII Century seeks to address this with the balancing statement, we believe many consumers will nonetheless be confused.

Simply stated, there is a real concern that consumers will continue to misunderstand the risks of using any nicotine-containing product, including approved nicotine replacement therapy (NRT) products, by believing that nicotine is the primary source of harm. According to research conducted on nationally representative surveys, a majority of Americans inaccurately believe that nicotine is a carcinogen and a primary source of harm associated with cigarettes¹. Approving XXII Century's proposed therapeutic claim may further widen the knowledge gap among consumers about the risks associated with using nicotine.

XXII's marketing strategy is inappropriate

One component of XXII Century's proposed marketing strategy for VLN™ cigarettes relies on the public health community and medical professionals to promote low-nicotine cigarettes as an intervention for people who smoke.

"22nd Century is relying upon the VLN(™) packaging and the public health community to promote the unique attributes of the product." (Section V. Labels, Labeling and Advertising.)

While some anti-tobacco organizations and some public health officials may eagerly promote low-nicotine cigarettes as an intervention for people who smoke, such a tactic is ill-advised considering the availability of other products which are verifiable low-risk and are currently available for purchase. Moreover, this strategy preys upon clinicians' misconceptions about nicotine and may reinforce erroneous beliefs about the risks associated with using any nicotine product.

¹ Andrea C Villanti, PhD, MPH, M Justin Byron, PhD, Melissa Mercincavage, PhD, Lauren R Pacek, PhD, Misperceptions of Nicotine and Nicotine Reduction: The Importance of Public Education to Maximize the Benefits of a Nicotine Reduction Standard, *Nicotine & Tobacco Research*, Volume 21, Issue Supplement_1, December 2019, Pages S88–S90, <https://doi.org/10.1093/ntr/ntz103>

Conclusion

CASAA urges FDA to reject XXII Century's MRTP application for VLN™ cigarettes on the grounds that approving the use of the proposed claim that this product "helps reduce your nicotine consumption" is (1) an unsupported therapeutic claim and (2) will further misinform consumers and medical professionals about the risk associated with nicotine.

While it may be appropriate for a company to introduce a new tobacco product with a lower nicotine content or a range of nicotine concentrations, even if it is a combustible product, XXII Century is seeking permission to make a health-related claim for a low-nicotine combustible product that does nothing to significantly reduce the exposure to toxic chemicals. Granting this request would be in direct conflict with the interests of public health.

Thank you for considering our comments.