

# Section V. Labels, Labeling and Advertising

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## V. Labels, Labeling and Advertising

The Tobacco Control Act specifies that an MRTP application shall include a description of any proposed advertising and labeling. TCA § 911(d)(1) (21 U.S.C. § 387k(d)(1)). The Act also requires submission of sample product labels and labeling. TCA § 911(d)(4) (21 U.S.C. § 387k(d)(4))<sup>1</sup> This section addresses both of these requirements.

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<sup>1</sup> The Federal Food, Drug, and Cosmetic Act defines “label” as “a display of written, printed or graphic matter upon the immediate container of any article” and “labeling” as “all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.” 21 U.S.C. §§ 321(k), 321(m). 22nd Century is applying these definitions for purposes of this application.

The cigarettes in this application are conventional cigarettes made with materials commonly used to manufacture cigarettes (filters, glues, cigarette papers, etc.). The only difference from conventional cigarettes is that these cigarettes are made with a tobacco strain that has been modified to reduce the nicotine content produced by the plant. For commercialization, the cigarettes will bear the brand name “VLN™”. The cigarettes will be sold as king size in regular and menthol versions.

#### A. Description of the Proposed Advertising and Labeling

FDA recommends in its “Draft Guidance for Industry, Modified Risk Tobacco Product Applications,” that the description of proposed advertising and labeling include “copies of any draft promotional materials (e.g. advertising and labeling) developed by the time of filing that the applicant expects will be used in marketing the MRTTP” and “[a] description of how you intend to communicate the proposed modified risk claim(s) to consumers.” (FDA MRTTP Draft Guidance, 2012, pp. 11-12 [[pg11](#)]).

22nd Century is submitting with this application draft product labels that have been developed. The labels were evaluated as part of 4 qualitative perception studies<sup>2</sup> and a Quantitative Study to Develop VLN™ Hypothetical Product Messages Among U.S. Adult Cigarette Smokers, Adult Former Cigarette Smokers and Adult Never Cigarette Users. The main results from these studies are summarized in Section VIII.E of this application.

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<sup>2</sup> The product labeling was changed in response to consumer comments during the different stages of the qualitative studies. The final labeling is included in the quantitative study.

## B. Communication of the Proposed Reduced Exposure Claim

The intention is to communicate the proposed reduced exposure claim(s) to adult smokers through the product labels (product packs). The labels on the cigarette packages, copies of which are provided with this application, will contain the reduced nicotine exposure claims. See file named, “Section\_V\_VLN Marketing Outline.pdf”, for information on proposed advertising of the products.

The principal reduced exposure claim is “95% LESS NICOTINE.” This claim will be prominently placed on the front and back of all packs. A supporting claim of “Helps reduce your nicotine consumption” will be placed under the “95% LESS NICOTINE” claim on the front of the packs.

The following disclaimer will appear on the front of each pack:

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

The following descriptive statement will appear on the back of each pack:

VLN smells, burns and tastes like  
a conventional cigarette, but  
greatly reduces your nicotine  
consumption.

The disclaimer was developed based on feedback from consumers during the qualitative research. Since the product is essentially just like a conventional cigarette, no specific instructions are needed for how to use the product.

VLN™ is not a unique product concept in the United States. A substantially similar product was marketed in the U.S. from about the years 2002 to 2009 by Vector Tobacco, LTD. under the brand name of “Quest®.” The principal claim was “virtually nicotine free.” Philip Morris USA also marketed a “denic” product under the brand name “Next” in 1989. 22nd Century is relying upon the VLN™ packaging and the public health community to promote the unique attributes of the product.

### C. Sample Product Labels and Labeling

This section contains the sample labels for the cigarettes which will be sold under the VLN™ brand name. The labels include cigarette packages, cartons, and cases.

VLN™ cigarettes will be sold in regular (king size) and menthol (king size) version. The package and carton labels are identical, except for the aspects that differentiate them as regular and menthol by name and by color. All exposure modification packaging variations contain the reduced exposure claim “95% Less Nicotine.” The cigarette package labels will comply with package marking requirements for cigarettes. The products will bear the required health warnings mandated by the Federal Cigarette Labeling and Advertising Act of 1966. It is contemplated that the 1-800 number appearing in the advertising materials, 1-800-225-1838, will also appear on the side of the package and carton under the P.O. Box address, in order to provide an additional means of contact for the smoker. Figure V.C-1. *VLN™ King Label*, and Figure V.C-2. *VLN™ Menthol King Label* below shows the flat images of the packs. Figure V.C-3

shows a 3D rendering of the pack. Figure V.C-4. *VLN™ King Carton Graphics*, and Figure V.C-5. *VLN™ Menthol King Carton Graphics*, show the carton graphics for the regular and menthol products. Figure V.C-6. *Case Graphics*, shows the graphics that will be printed on the case. A mark will be placed on the case to indicate if the case contains regular or menthol VLN™ cigarettes.

Figure V.C-1. VLN™ King Label

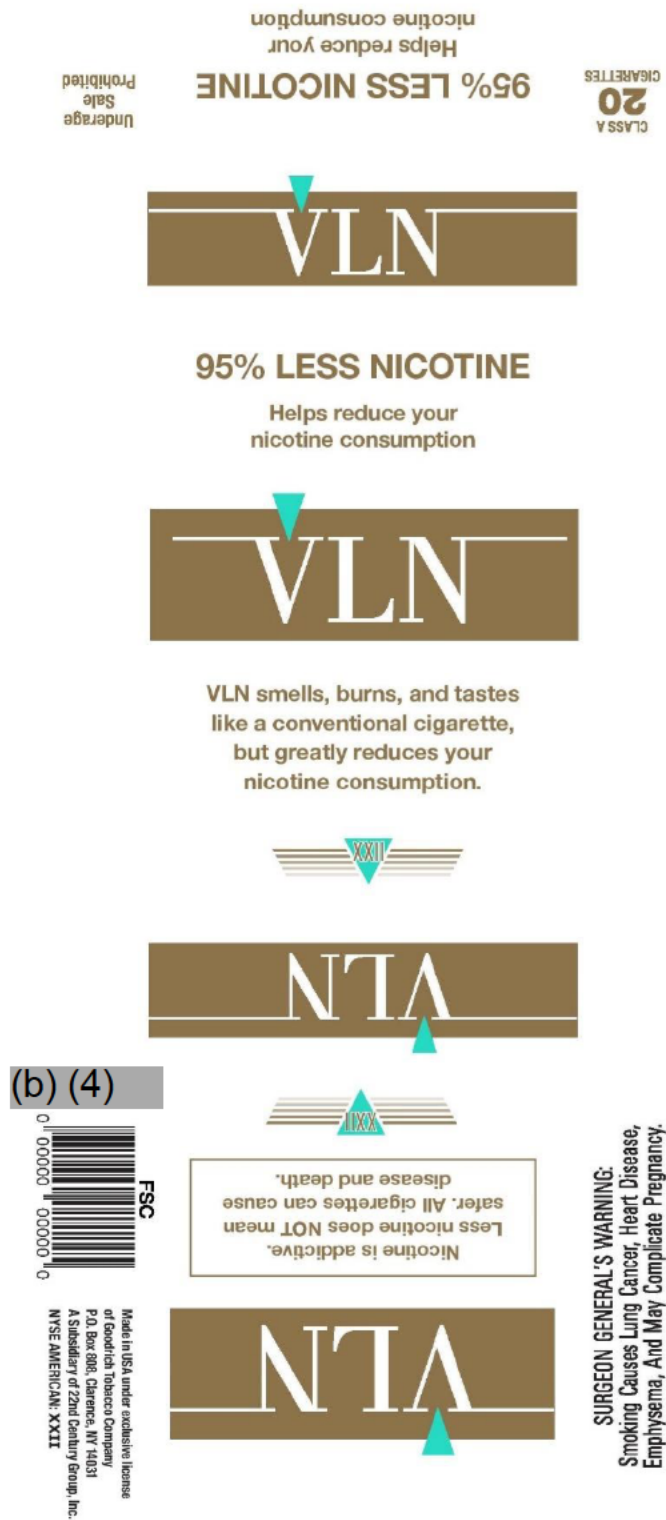


Figure V.C-2. VLN™ Menthol King Label

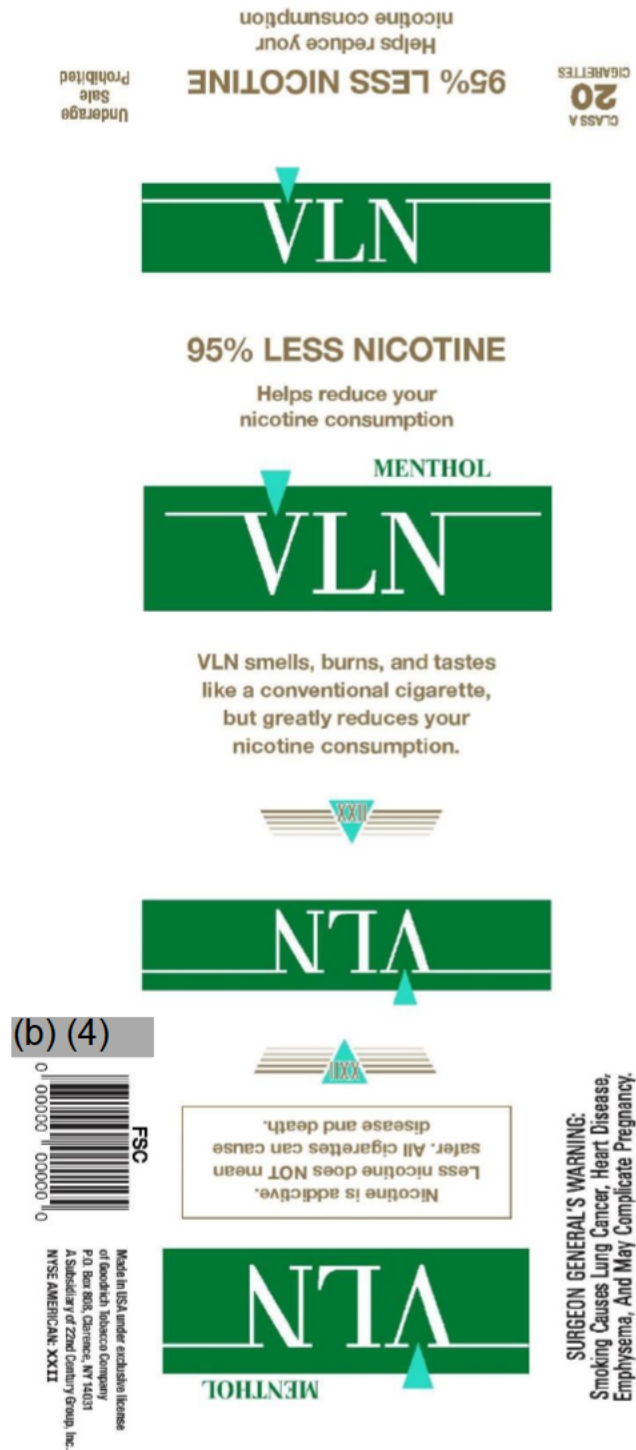


Figure V.C-3. 3D Rendering of Pack





Figure V.C-4. VLN™ King Carton Graphics

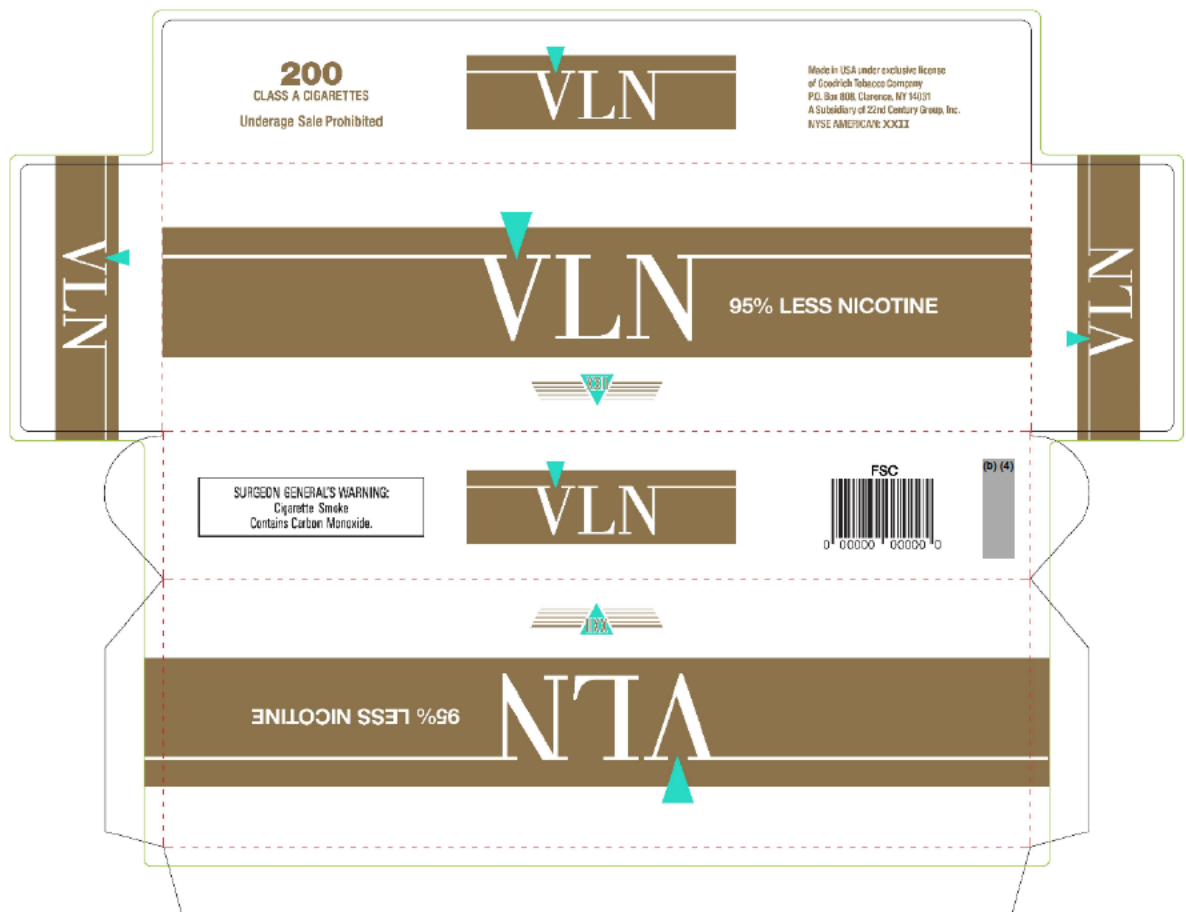


Figure V.C-5. VLN™ Menthol King Carton Graphics

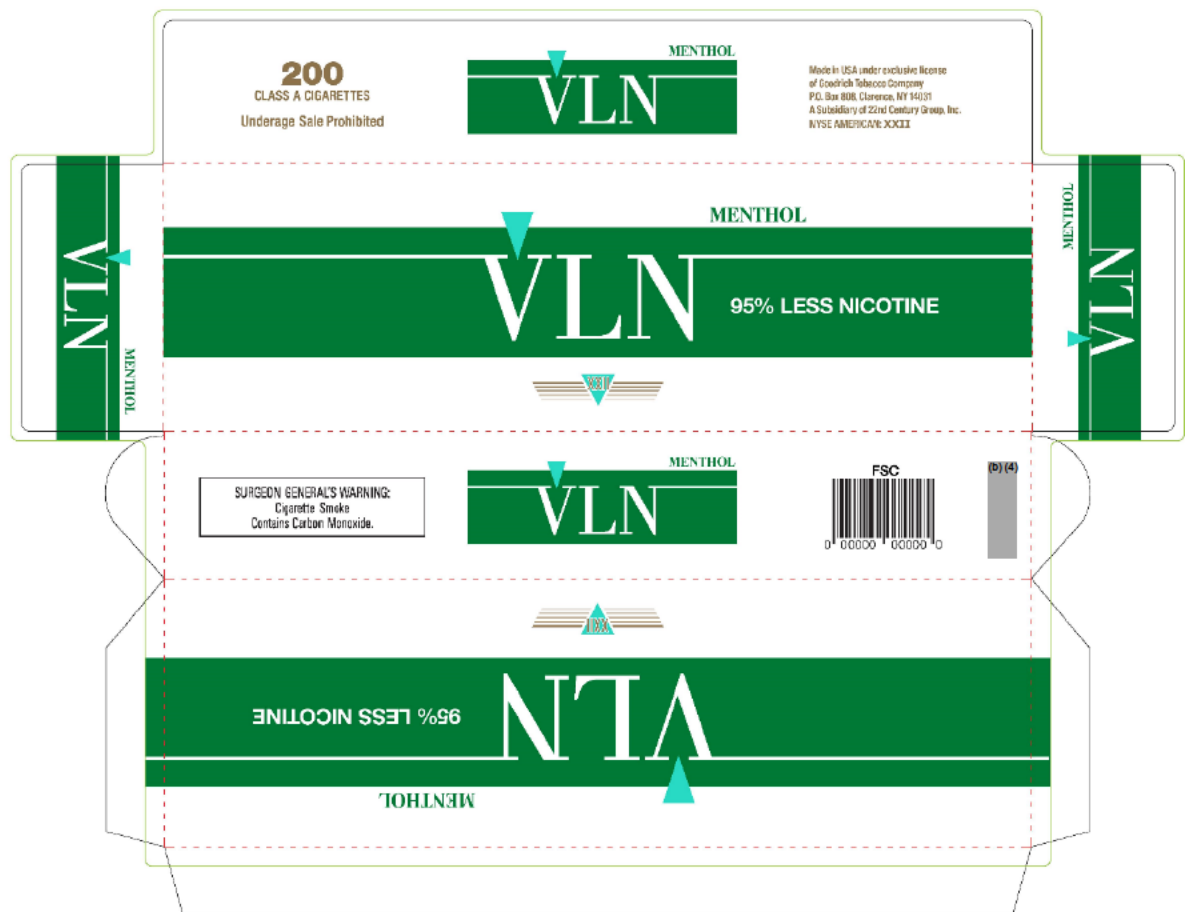
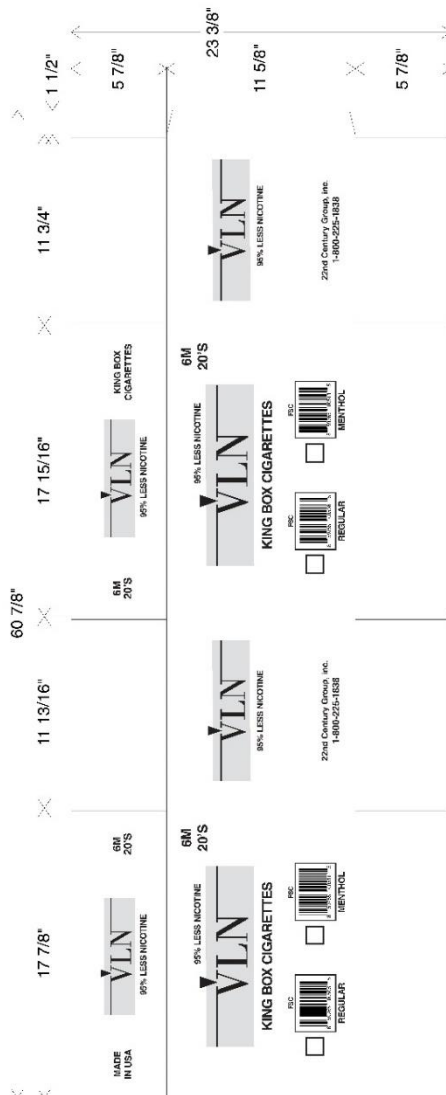


Figure V.C-6. Case Graphics



## D. Bibliography

[M/A/R/C Research. 2018.](#) “Qualitative Study to Develop PARE/VLN Claims within the United States. Phases 1, 2, 3, and 4.”

[US Department of Health and Human Services, Food and Drug Administration, Center for tobacco Products. 2012.](#) “Modified Risk Tobacco Product Applications Draft Guidance.”

Federal Cigarette Labeling and Advertising Act. 15 CFR Chapter 36, §1333 - §1341 (1966).