

March 7, 2022

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Food and Drug Administration
Center for Tobacco Products
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

SUBJECT: Labeling and Advertising Materials for Submission Tracking Numbers – PM0000593 through PM0000612, ZYN PMTA Amendment

Dear Sir or Madam:

Swedish Match USA, Inc. (“Swedish Match”, “our” or “we”) is submitting an amendment to the PMTA applications listed below, which are currently under scientific review with the Center for Tobacco Products (“CTP”). The purpose of this amendment is to address comments from the CTP concerning the use of the term “tobacco-free” on product labeling and in marketing materials, and to outline the steps that Swedish Match has taken to ensure that the phrase will be completely removed from all materials in 2022.

STN	ZYN Product
PM0000593	ZYN Cool Mint 3 mg
PM0000594	ZYN Cool Mint 6 mg
PM0000595	ZYN Peppermint 3 mg
PM0000596	ZYN Peppermint 6 mg
PM0000597	ZYN Spearmint 3 mg
PM0000598	ZYN Spearmint 6 mg
PM0000599	ZYN Wintergreen 3 mg
PM0000600	ZYN Wintergreen 6 mg
PM0000601	ZYN Citrus 3 mg
PM0000602	ZYN Citrus 6 mg

PM0000603	ZYN Coffee 3 mg
PM0000604	ZYN Coffee 6 mg
PM0000605	ZYN Cinnamon 3 mg
PM0000606	ZYN Cinnamon 6 mg
PM0000607	ZYN Smooth 3 mg
PM0000608	ZYN Smooth 6 mg
PM0000609	ZYN Chill 3 mg
PM0000610	ZYN Chill 6 mg
PM0000611	ZYN Menthol 3 mg
PM0000612	ZYN Menthol 6 mg

For reference, there have been three prior submissions to the FDA for the ZYN products referenced.

- Initial Premarket Tobacco Application (“PMTA”) submission for ZYN to the FDA dated March 4, 2020. Referenced by the STNs assigned above.
- Swedish Match response to the Agency’s Deficiency Letter dated, July 24, 2020. Addressed deficiency questions, information requests, as well as Environmental Assessment and Confidential Appendices.
- 90-Day Notice submission dated December 1, 2020. Newly named ZYN Menthol tobacco products, identical to previously marketed ZYN Fresh tobacco products. Notification of a name/label change, not requiring a separate path to market application.

We appreciate your consideration and evaluation of the Amendment found below, concerning our PMTAs identified in the table above. If you should have any questions, please let me know.

Sincerely yours, (b) (6)

(b) (6)

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Document Attachments

Appendix A – ZYN PMTA Amendment Narrative

Appendix B – ZYN PM0000593 - PM0000612 Advertising Materials Product Labeling

SUBJECT: Labeling and Advertising Materials for Submission Tracking Numbers PM0000593 through PM0000612, ZYN PMTA Amendment

In response to comments from the Agency, Swedish Match submits this Amendment to its Premarket Tobacco Product Application for ZYN Nicotine Pouches, Submission Tracking Numbers – PM0000593-PM0000612. The purpose of this Amendment is to specifically address the Agency's concerns regarding the use of the phrase "tobacco-free" in proposed advertising and labeling materials for these applications, as raised in the Deficiency Letter issued by the Agency on July 24, 2020. This amendment outlines the steps that Swedish Match has taken to complete the removal of the phrase "tobacco-free" from all labeling and marketing materials.

Beginning in (b) (4), Swedish Match initiated the process to remove the phrase "tobacco-free" from all consumer-facing marketing communications. This process included inter-departmental coordination efforts and communication with third party agencies. As it stands, there are no new marketing materials containing the phrase "tobacco-free" in development and this is now a standard part of our marketing policy moving forward. This process has entailed redeveloping all materials to suspend use of the phrase "tobacco-free." Transition to removal of the phrase "tobacco-free" has been completed for the following materials: Point of Sale, age-restricted digital media (historical posts referencing "tobacco-free" have also been deleted), e-mail and direct mail to consumers, the zyn.com website, trade marketing documents, and trade and print advertising. Swedish Match has worked with its third-party agencies to conduct a full audit of digital advertising assets to ensure the complete removal of the phrase "tobacco-free", no later than March 20, 2022.

Also beginning in (b) (4), our Field Sales organization was instructed to remove and replace any advertising materials containing the phrase "tobacco-free" located at retail points of sale. This instruction was further reiterated to all Sales personnel in (b) (4). At this time, we believe that the majority of these items have been removed from retail points of sale. While development of new Point of Sale material that does not contain the phrase "tobacco-free" has been completed, Swedish Match recognizes that there may be some instances of prior artwork still lingering in market. Over the next three months, Sales employees will actively work to remove and destroy any remaining legacy materials containing the phrase "tobacco-free." These will be replaced with the new materials which have been developed without the phrase "tobacco-free." To facilitate this transition within our Sales organization, custom Point of Sale templates were updated and images of previously used materials containing the phrase "tobacco-free" were removed from internal image galleries. Further, all Point of Sale materials containing the phrase "tobacco-free" that remained in warehouse storage were destroyed in (b) (4).

Finally, the process of removing the phrase “tobacco-free” from proposed product can labels commenced in (b) (4). At this time new artwork for ZYN packaging was initiated for the can labels, the roll wrap, and the case in which the product is sold to wholesalers. Images of the new proposed product packaging are attached hereto as **Appendix B** for Agency review. The proposed product has three can labels: 1) A top label which is consumer facing at point of sale, 2) a bottom label, and 3) a side label. As of this writing, the phrase “tobacco-free” is no longer present on the top or bottom labels. The new side label artwork which eliminates the phrase “tobacco-free” has been created and forwarded to our suppliers for creation of new printing plates to enable this changeover so that Swedish Match can incorporate the new packaging into our manufacturing facility. Swedish Match has requested that these changes be implemented as soon as possible. Barring additional supply-chain constraints the new plates should be implemented in (b) (4), allowing for run through of existing materials we expect to manufacture 100% packaging that does not contain the phrase “tobacco-free” by (b) (4). We acknowledge that the current packaging may remain in the market until retailers are able to achieve full sell-off and products with the new proposed packaging have fully been circulated into the market. Based upon estimates of existing materials, wholesale inventory, and sales velocity, the proposed product labeling would not include the phrase “tobacco-free” in inventory or Point of Sale by (b) (4). Prior to that time, since Point of Sale material will not include the phrase “tobacco free”, ZYN cans are front label facing at retail and are typically sold in a behind the counter setting, consumers will not be exposed to “tobacco- free” language when making a purchase decision.

In summary, Swedish Match began the process of removing the term “tobacco-free” from ZYN product labeling and marketing materials in (b) (4). We are also confident that these changes will not impact our contention that the continued marketing of the proposed product is appropriate for the protection of public health. Despite procurement and logistical complexities, our manufacturing and marketing teams have already been able to make progress toward addressing CTP’s concerns in a relatively short period of time. We are able to provide the Agency with progress updates as we complete this transition and are available to further discuss the contents of this amendment with the Agency.

¹ It is difficult to provide a precise estimate of product inventory at any given time. (b) (4). While the transition to new labeling will begin much sooner, we expect complete replacement of cans with the “tobacco-free” label by (b) (4).



Top Label

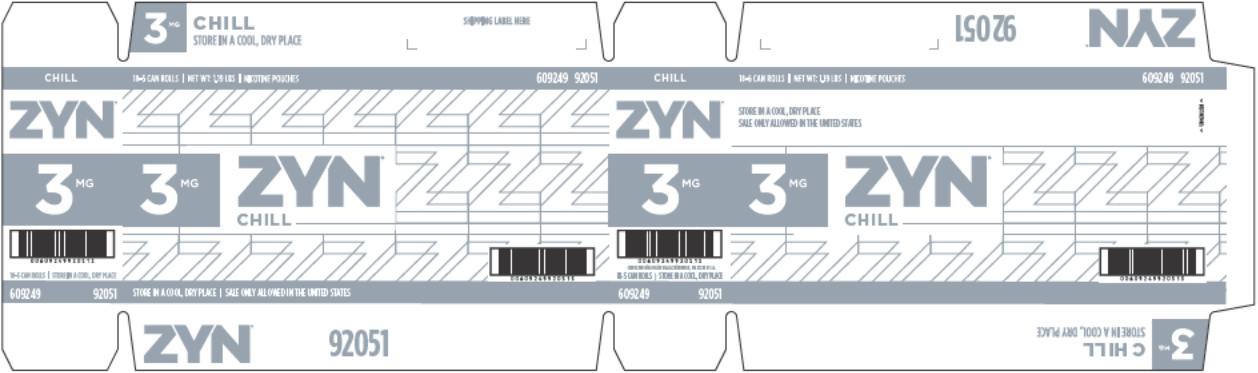


Side Label



Bottom Label

Roll Label



Case (15%)

PM0000610



Top Label

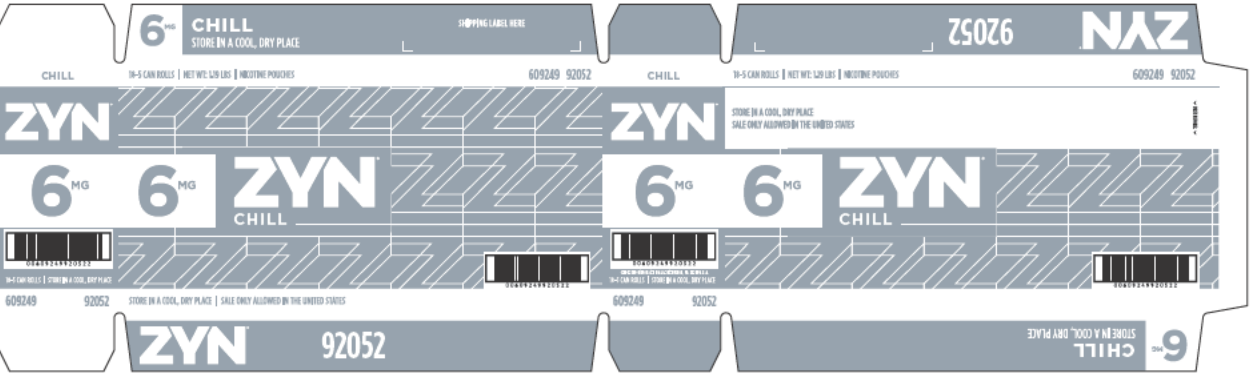
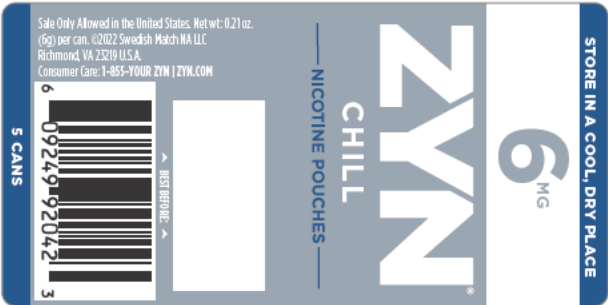


Side Label



Bottom Label

Roll Label



Case (15%)



Top Label

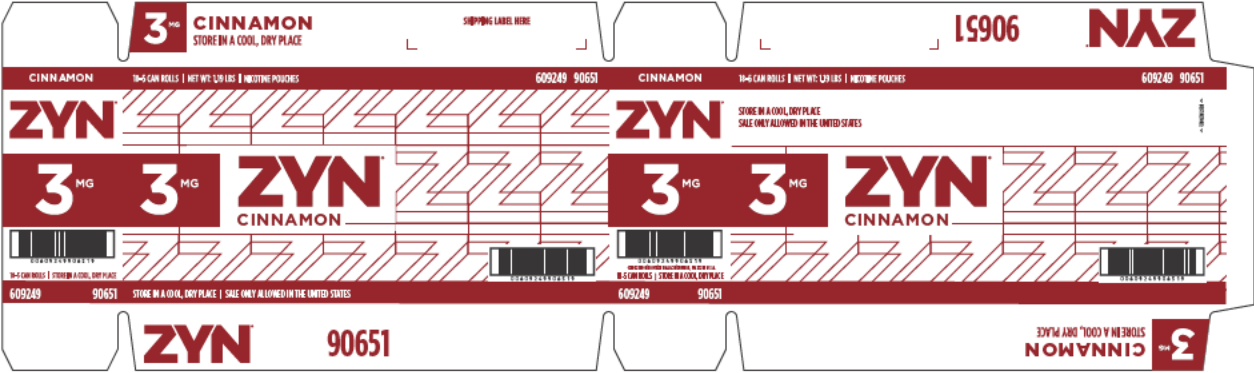


Side Label



Bottom Label

Roll Label



Case (15%)

CINNAMON 06

PM0000606



Top Label

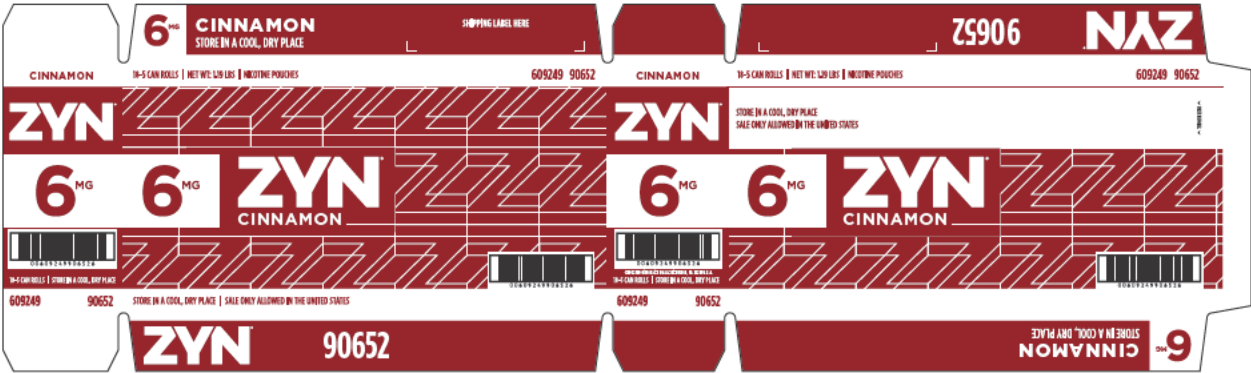


Side Label



Bottom Label

Roll Label



Case (15%)



Top Label

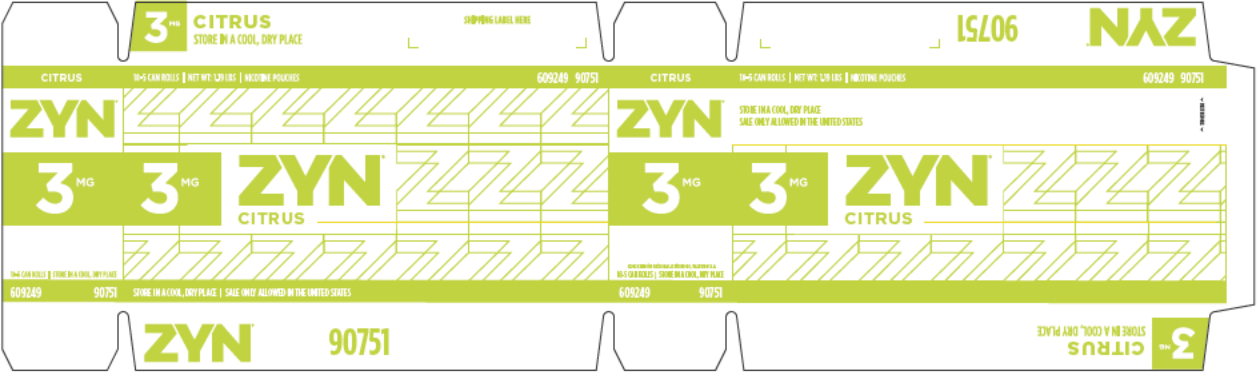
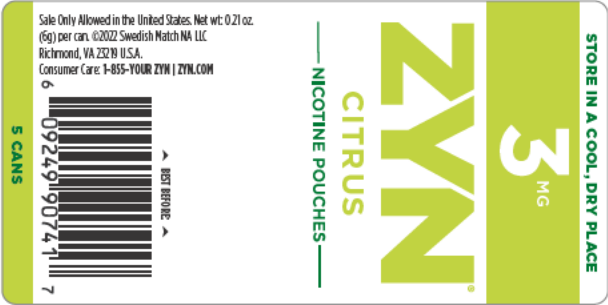


Side Label



Bottom Label

Roll Label



Case (15%)

CITRUS 06

PM0000602



Top Label

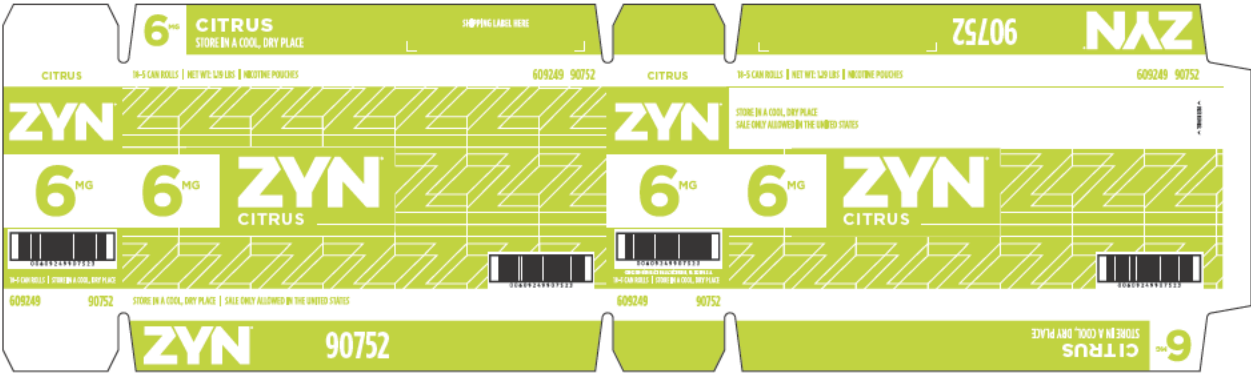
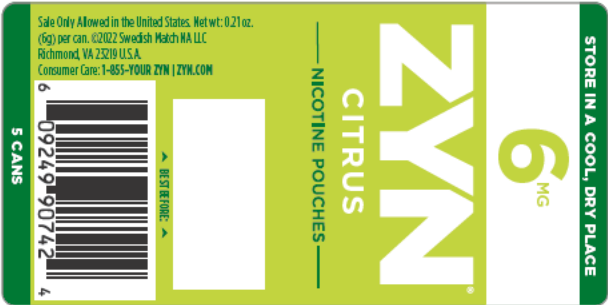


Side Label



Bottom Label

Roll Label



Case (15%)

COFFEE 03

PM0000603



Top Label

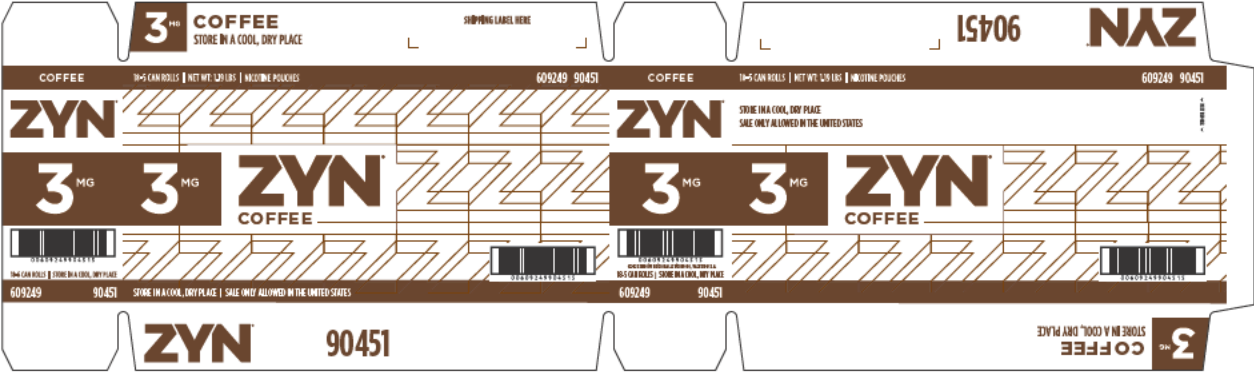
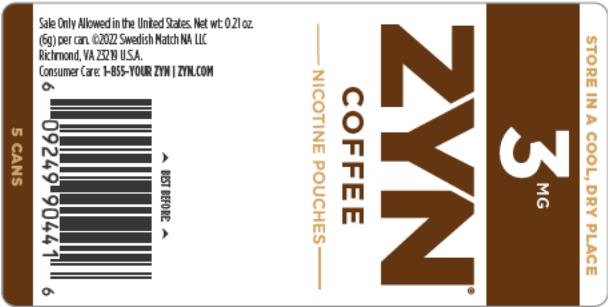


Side Label



Bottom Label

Roll Label



Case (15%)

COFFEE 06

PM0000604



Top Label

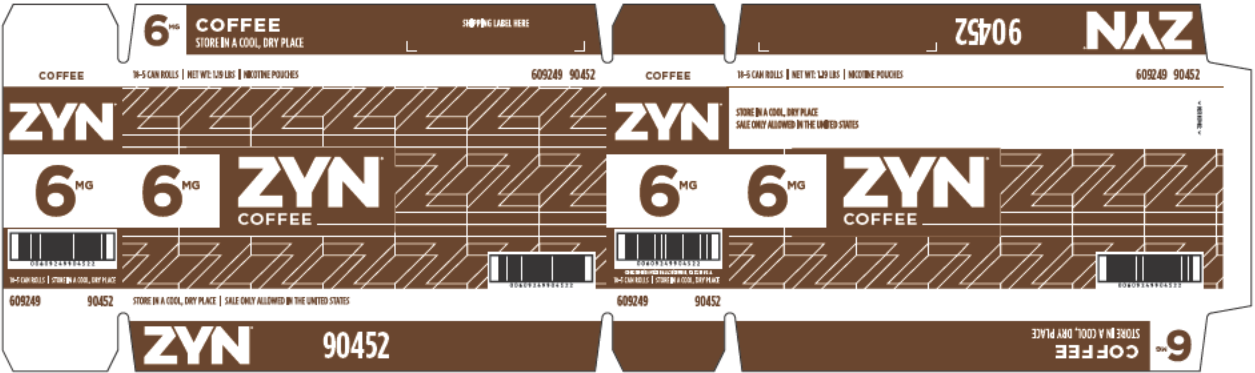
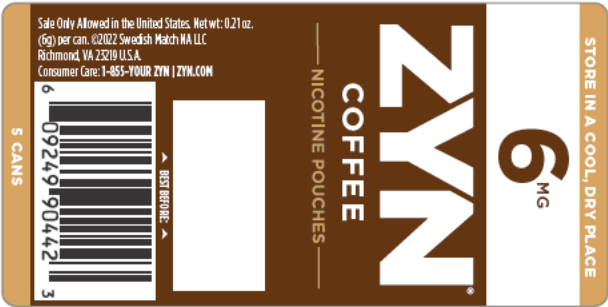


Side Label



Bottom Label

Roll Label



Case (15%)

COOL MINT 03

PM0000593



Top Label

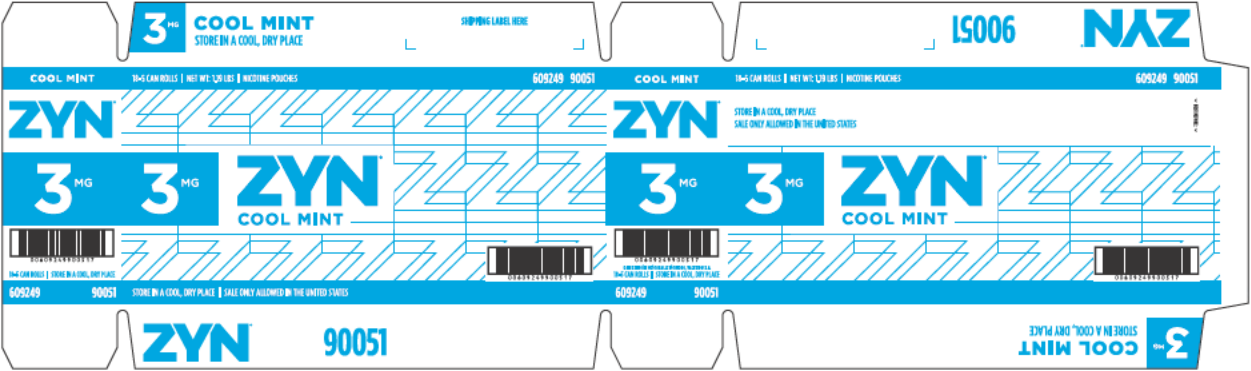


Side Label



Bottom Label

Roll Label



Case (15%)

COOL MINT 06

PM0000594



Top Label

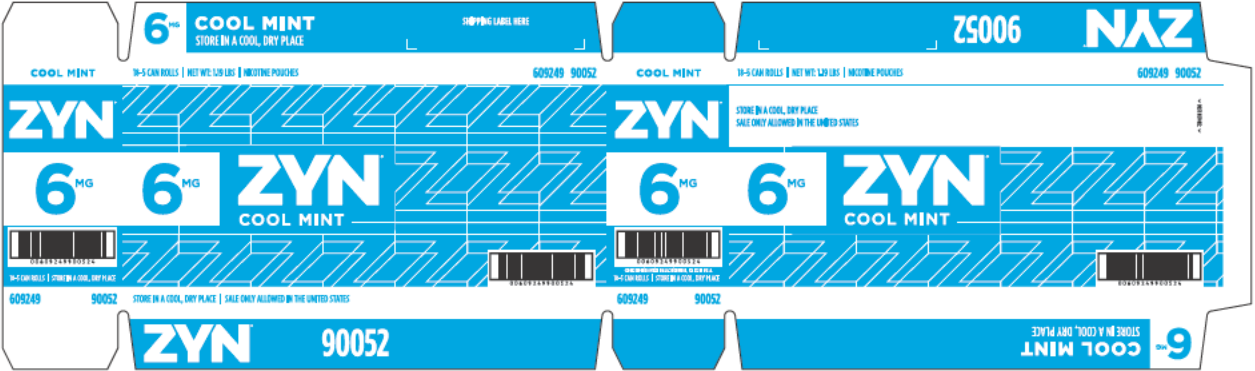


Side Label



Bottom Label

Roll Label



Case (15%)

MENTHOL 03

*12/1/20 - 90-Day Notice Name/Label Change: "Fresh" to "Menthol"

PM0000611



Top Label

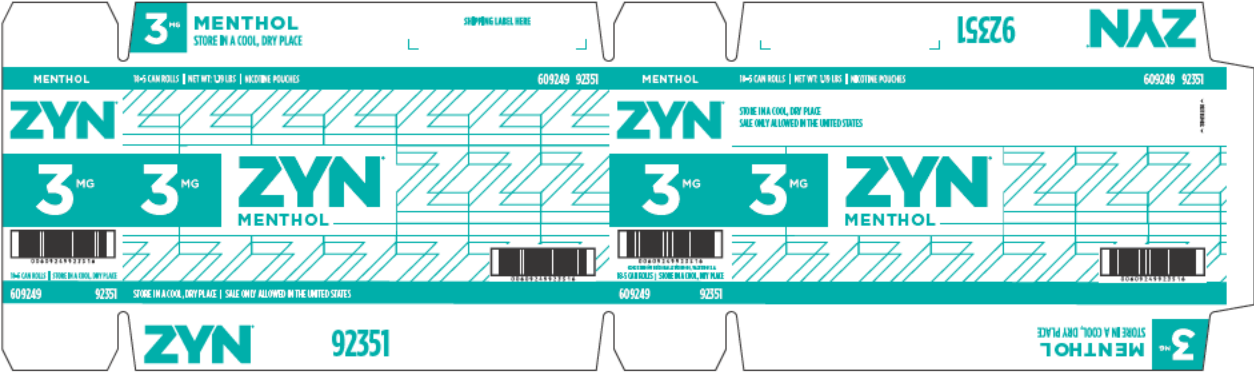


Side Label



Bottom Label

Roll Label



Case (15%)

MENTHOL 06

PM0000612

*12/1/20 - 90-Day Notice Name/Label Change: "Fresh" to "Menthol"



Top Label

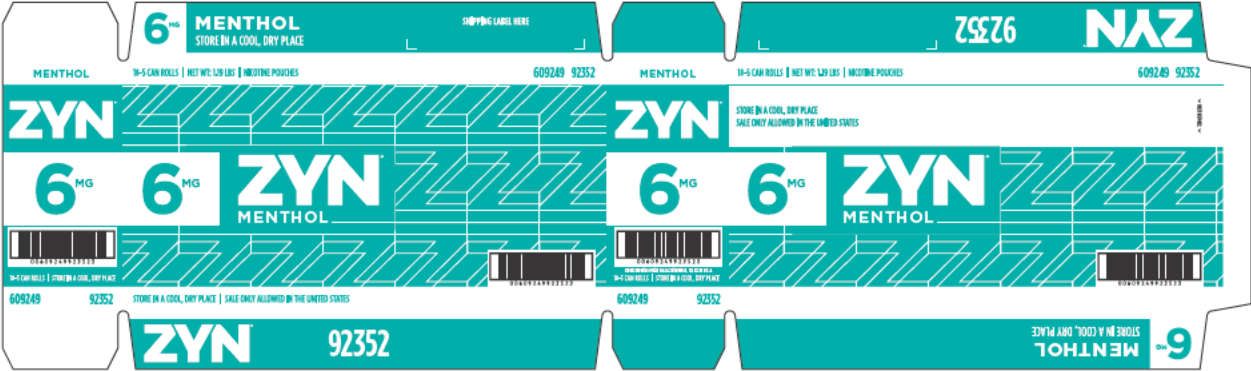
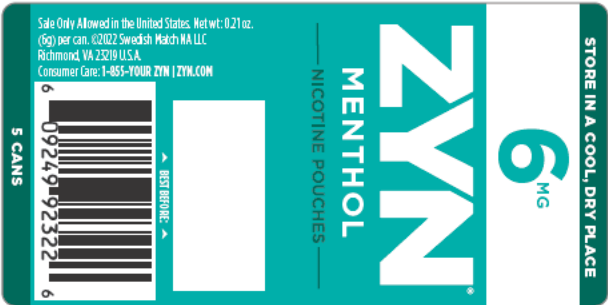


Side Label



Bottom Label

Roll Label



Case (15%)

PEPPERMINT 03

PM0000595



Top Label

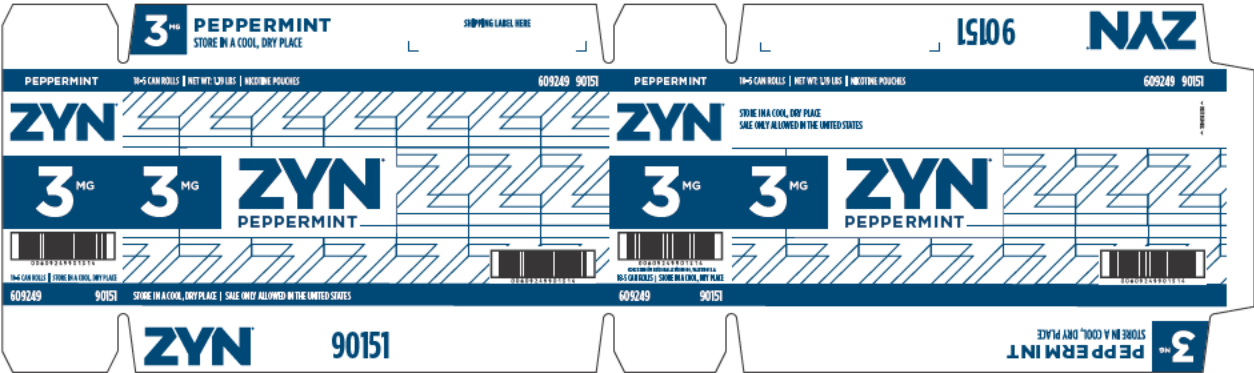


Side Label



Bottom Label

Roll Label



Case (15%)

PEPPERMINT 06

PM0000596



Top Label

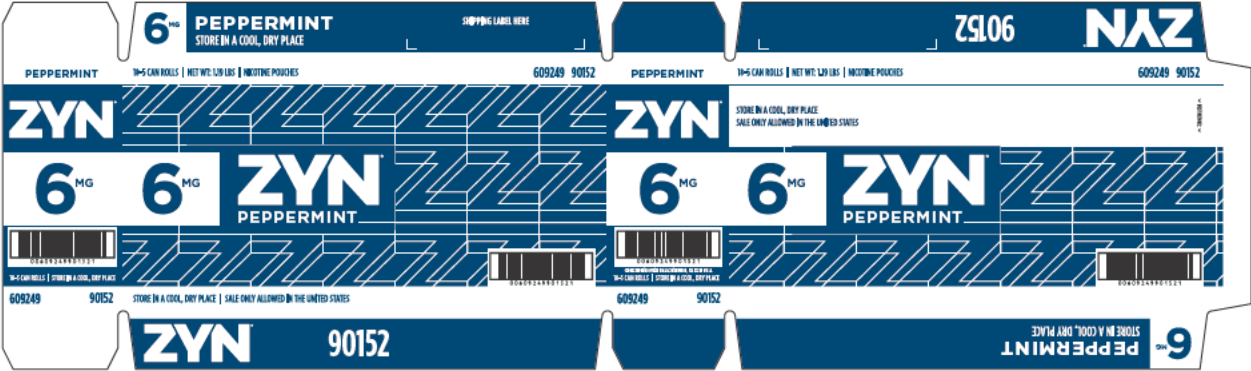
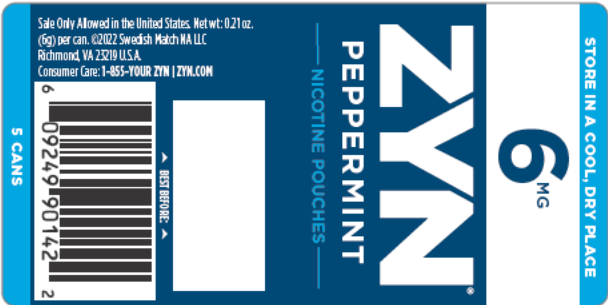


Side Label



Bottom Label

Roll Label



Case (15%)

SMOOTH 03

PM0000607



Top Label

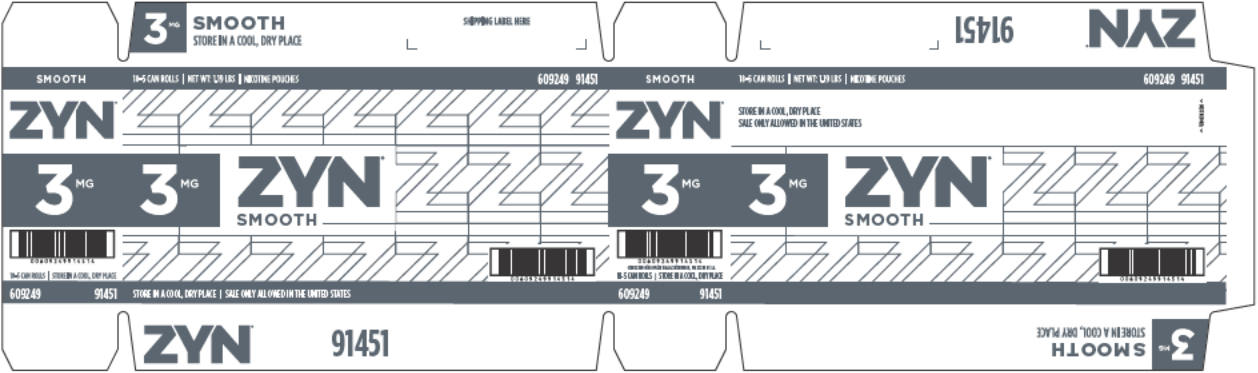


Side Label



Bottom Label

Roll Label



Case (15%)

SMOOTH 06

PM0000608



Top Label

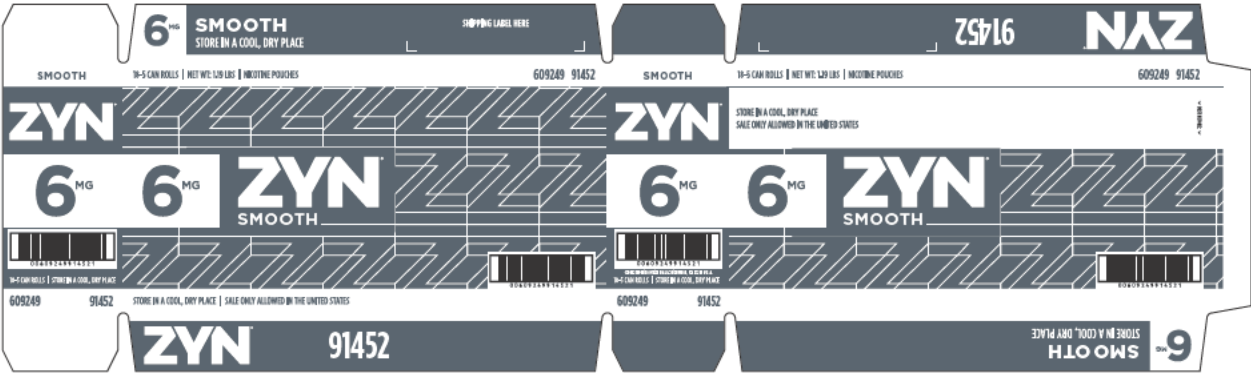
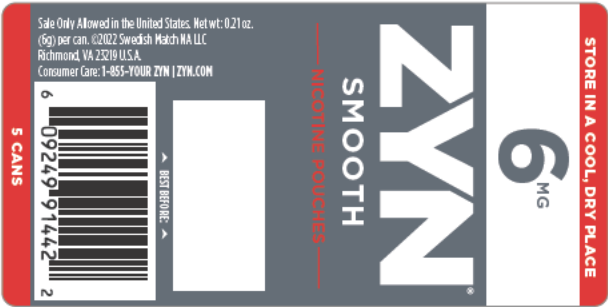


Side Label



Bottom Label

Roll Label



Case (15%)

SPEARMINT 03

PM0000597



Top Label

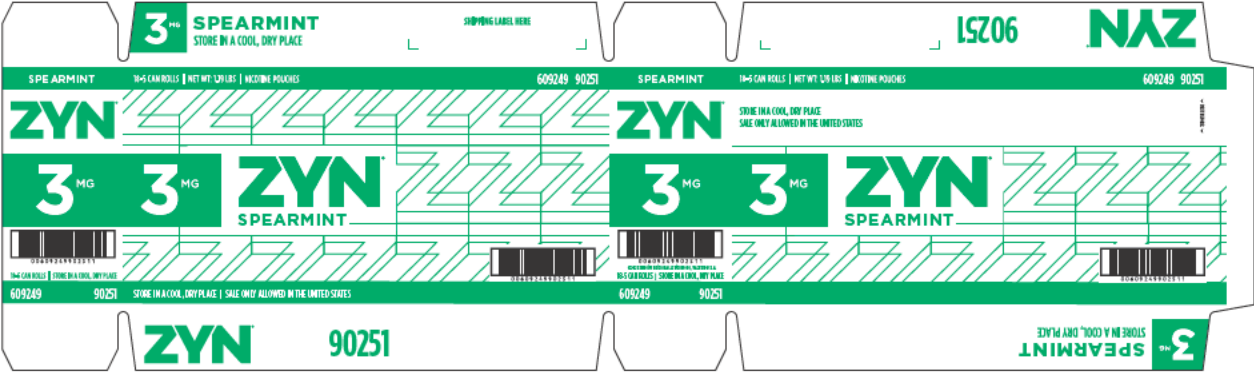


Side Label



Bottom Label

Roll Label



Case (15%)

SPEARMINT 06

PM0000598



Top Label

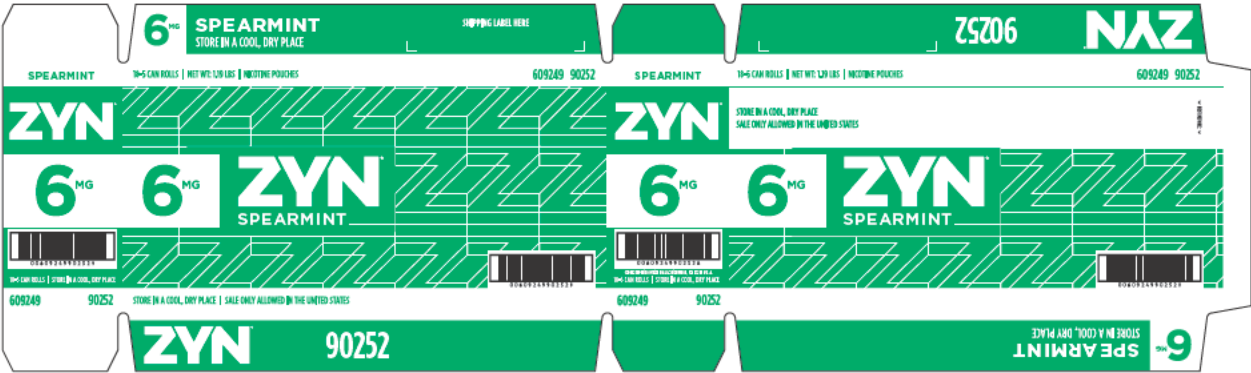


Side Label



Bottom Label

Roll Label



Case (15%)

WINTERGREEN 03

PM0000599



Top Label

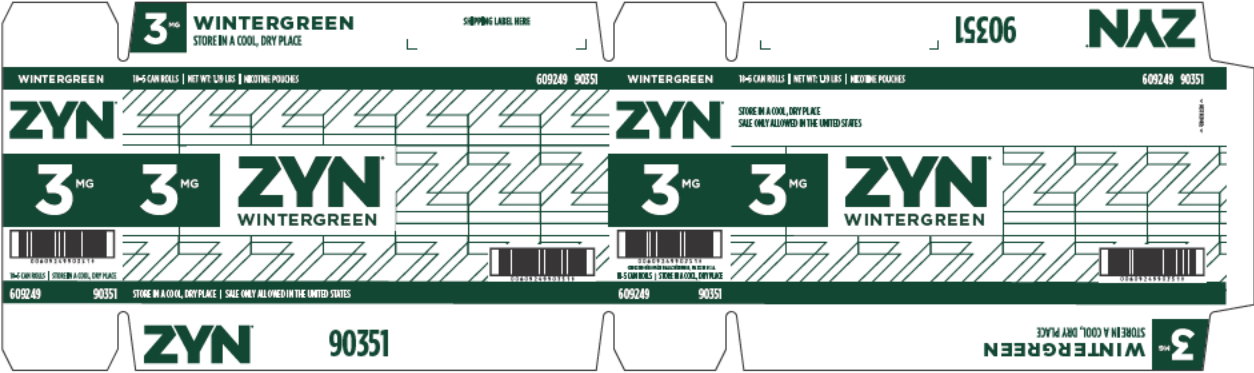


Side Label



Bottom Label

Roll Label



Case (15%)

WINTERGREEN 06

PM0000600



Top Label

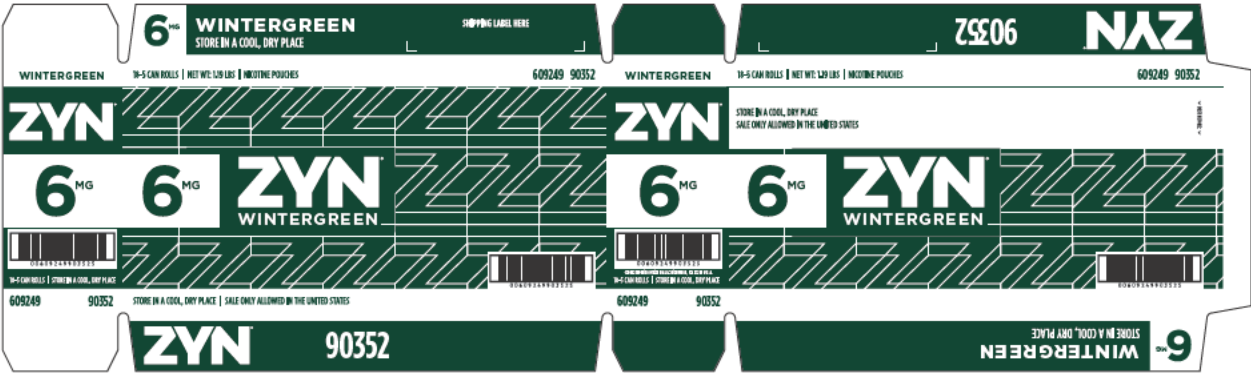


Side Label



Bottom Label

Roll Label



Case (15%)