

Temporary Compliance Waiver Notice

The linked files may not be fully accessible to readers using assistive technology. We regret any inconvenience that this may cause our readers. In the event you are unable to read the documents or portions thereof, please email AskCTP@fda.hhs.gov or call 1-877-287-1373.



Rebecca A. Rivas
Sr. Director
Regulatory Submissions

March 9, 2022

VIA CTP PORTAL

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

Re: RESPONSE TO CTP REQUEST FOR INFORMATION for MR0000108

Dear Sir/Madam:

Altria Client Services LLC (ALCS), on behalf of U.S. Smokeless Tobacco Co. LLC,¹ provides the following responses to an email request received on March 7, 2022 from the Center for Tobacco Products (CTP), Office of Science, regarding our responses to a Deficiency Letter dated September 29, 2021 for MR0000108.

Request 1

[REDACTED] (b) (4)
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Please provide all labels and labeling for the product as they are proposed to be used. Include full-color copies of all panels (e.g., top, bottom, side) that reflect the actual size and include any variation in the labeling due to the different product colors. Note that the product's labeling will have to comply with smokeless tobacco warning requirements such as those regarding size,

¹ U.S. Smokeless Tobacco Co. LLC (USSTC) is a wholly owned subsidiary of Altria Group, Inc. Altria Client Services LLC (ALCS), provides certain services, including regulatory affairs, research and development, and regulatory sciences to the Altria family of companies. "We" or similar pronouns are used throughout to refer to USSTC.

TRADE SECRET/CONFIDENTIAL COMMERCIAL INFORMATION

Altria Client Services LLC
601 East Jackson Street
Richmond, Virginia 23219

[REDACTED] (b) (6)
[REDACTED]

placement on display panels, and contrast with other printed material on the package. Also, if you have drafted additional advertisements with the (b) (4) (in addition to the print advertisement noted above), please provide those in addition to all labels and labeling mentioned above.

Response to Request 1

In *Appendix A*, we provide full-color copies of the top, bottom,² and side labels for (b) (4). We also provide a copy of the shrink wrap for 5-can rolls of (b) (4). *Appendix A* reflects the true colors of the labels, which are (b) (4). At this time, we do not have any additional proposed advertising (b) (4) other than the sample advertisement provided in our September 29, 2021 Response to Deficiency Letter for MR0000108.

Request 2

In the amendment, you refer to a (b) (4). Please let us know the site's address, name, FDA Establishment Identifier (FEI, if any), and whether the site is registered with FDA.

Response to Request 2

In Response to Question 5b. of CTP's March 26, 2021 Deficiency Letter, we provided a description of locations where we receive burley tobacco which included a receiving station in (b) (4). See September 29, 2021 Response to Deficiency Letter for MR0000108 at 21. (b) (4) receiving station is an independent tobacco warehouse that receives burley tobacco and, pursuant to Food, Drug and Cosmetic Act, Section 901(c)(2)(A), is outside the scope of FDA's tobacco products authority. We note that USSTC's finished smokeless tobacco product manufacturing facility is USSTC- Nashville, 800 Harrison Street, Nashville, TN 37203, FEI# 3003799544.

² USSTC may use a bottom can label to communicate the proposed modified risk claim to adult tobacco consumers. See Copenhagen Fine Cut Snuff MRTPA, MR0000108, Section 4.1.4.7.

These responses contain trade secret and confidential commercial information that USSTC considers to be proprietary and highly sensitive, and which is protected from disclosure under FDCA §§ 301(j) and 906(c) (21 U.S.C. §§ 331(j) and 387f(c)), the Trade Secrets Act (18 U.S.C. § 1905), the Freedom of Information Act (“FOIA”) (5 U.S.C. § 552), and FDA’s implementing regulations, 21 C.F.R. Part 20. If FDA receives a request for these records and tentatively determines that any portion of the submission is disclosable, USSTC requests that FDA provide notice and an opportunity for USSTC to object to any disclosure in accordance with 21 C.F.R. §§ 20.47 and 20.61. USSTC reserves all legal rights to protect against public disclosure of its trade secret and confidential commercial information and to seek legal recourse against anyone who discloses such information without legal authorization.

Sincerely,

(b) (6)

A large rectangular gray box redacting the signature and name of the sender.

Attachment

TRADE SECRET/CONFIDENTIAL COMMERCIAL INFORMATION

(b) (4)

