DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

FDA Submission Tracking Number (STN): AP0000043
APPEAL GRANTED

April 17, 2019

Commonwealth Brands, Inc.
ATTENTION: Carole Folmar, Director of Regulatory & Scientific Affairs
714 Green Valley Road
Greensboro, NC 27408

Re: Response to Request for Supervisory Review – SE0002732-SE0002736, SE0002739-SE0002740

Dear Ms. Folmar:

I have completed the review of your request for supervisory review, received March 9, 2018, under Title 21 of the Code of Federal Regulations (C.F.R.) section 10.75. Commonwealth Brands, Inc. ("CBI") requested supervisory review of seven Not Substantially Equivalent (NSE) orders that the Center for Tobacco Products (CTP) issued on January 4, 2018, regarding the following tobacco products:

- SE0002732 – Montclair Blue 100s Box
- (b) (4)
- SE0002734 – Montclair Gray 100s Box
- SE0002735 – Montclair Gray King Box
- SE0002736 – Montclair Menthol Green 100s Box
- SE0002739 – Montclair White 100s Box
- SE0002740 – Rave Gold 100s Box

This letter reflects the decision on your request by CTP.

As Center Director Mitch Zeller's designee to decide Office of Science (OS)-related appeals accepted by the Office of the Center Director, I have reviewed OS's decision to find the subject products not substantially equivalent to their respective predicate products. As part of this review, I have consulted with senior representatives from OS.

After reviewing all the information submitted in your appeal request and consulting with senior representatives in OS, your appeal is granted. I describe below the regulatory history for the appealed submissions and the basis for my decision.

Regulatory History

On March 18, 2011, CBI submitted several provisional[1] SE reports, including the seven SE reports at issue in this appeal. Scientific review of the SE reports began on August 26, 2015.

On October 5, 2015, after reviewing the initial SE reports, OS sent CBI an Advice/Information Request letter ("A/I letter") requesting a range of information about the new and predicate products, including target specifications, upper and lower range limits and test data for tobacco filler mass, oven volatiles, filter efficiency, cigarette draw resistance, as well as information about the cigarette paper. CBI responded to the A/I letter on December 3, 2015.

On March 9, 2016, after reviewing CBI's responses, OS issued a Preliminary Finding letter ("PFind letter"), listing deficiencies that included: lack of target specifications, upper and lower range limits, and test data for total denier, denier per filament, and filter density; an increase in tar, nicotine, carbon monoxide (TNCO) levels in some of the new products, and the absence of scientific evidence and rationale explaining why such increases did not cause the new tobacco products to raise different questions of public health; and (b) (4) [redacted] CBI responded to the PFind letter on April 8, 2016.

On January 4, 2018, after reviewing CBI's responses, OS issued NSE order letters for SE0002732-2736 and 2739-2740.

On March 9, 2018, CBI filed an appeal request for supervisory review of the January 4, 2018, NSE orders, in accordance with 21 CFR § 10.75. In the appeal request, CBI argued that "it was inappropriate to arbitrarily terminate the engineering review by asking further questions or citing the need for additional information and data without providing CBI with an opportunity to respond" and that "the determinations of the chemistry, toxicology, and social sciences review staffs rendered the engineering review irrelevant to the evaluation of whether the new tobacco products raise different questions of public health."[2]

CBI has requested that CTP vacate the NSE orders, and (1) for SE0002732, SE0002736, SE0002739, and SE0002740, order OS to issue SE orders, and (2) for (b) (4) [redacted], SE0002734, and SE0002735, remand the SE reports to OS for additional opportunity for CBI to address the deficiencies.

CBI also requested a meeting regarding this appeal, and a meeting was held on April 11, 2018. The meeting was attended by Rob Wilkey, Katherine Ciambrone, and Carole Folmar of ITG Brands; Ben Haas, John Manthei, Phil Perry, Andrew Prins, and Nate Beaton of Latham & Watkins LLP; Richard Turman, Shawn Fultz, Dan Reed, Rohit Mathew, Dhanya John, Khemry Min, Allison Monyei, and Nathan Hurley of CTP; and Jessica Greenbaum and Will Thanhauser

[1] To qualify as a provisional SE report, an SE report must be: (i) for a new tobacco product first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007, and prior to March 22, 2011; and (ii) submitted to FDA by March 22, 2011. *See* Food, Drug & Cosmetic Act (FD&C Act) section 910(a)(2)(B).

[2] Appeal Request letter from CBI to FDA, received March 9, 2018, at 4, 5.

of the Office of General Counsel, Department of Health and Human Services. Counsel for CBI requested an additional meeting during the course of this appeal, and a meeting was held on August 27, 2018.

Decision

As described below, I have determined that the SE reports for SE0002732, 2734-2736, and 2739-2740 contain sufficient information to demonstrate that the differences between the predicate tobacco products and respective new tobacco products, as described in the reports, do not cause the new tobacco product to raise different questions of public health. However, (b) (4) [redacted]

Engineering Deficiencies

For all the subject SE reports, the NSE decisions included Engineering deficiencies related to a lack of information. On appeal, OS has determined that this information either could be calculated by OS through other information submitted by CBI or is not necessary to determine substantial equivalence. As to this second point, OS has concluded that the result of any differences in certain design parameters between the subject new and predicate tobacco products would be a deferral to the chemistry discipline; and, since the chemistry discipline concluded that CBI demonstrated that the subject new tobacco products were substantially equivalent to their corresponding predicates from a chemistry perspective, this engineering information is not needed here. As such, the Engineering deficiencies do not stand.[3] For SE0002732, 2736, 2739, and 2740, the Engineering deficiencies were the sole deficiencies supporting the NSE decisions; accordingly, the NSE orders for these SE reports do not stand.

Surrogate Product Deficiencies

For SE0002734-2735, there was an additional deficiency related to the use of surrogate-product data in lieu of data for the new products described in the SE reports.[4] Specifically, the NSE orders for these SE reports concluded that CBI failed to clarify whether the surrogate tobacco products were identical in terms of tobacco composition, ingredients, additives, and materials, to the new tobacco products. CBI stated in its response to the PFind letter that the surrogate products "have an identical construction (with the exception of brand identifiers on the tipping paper), design parameters, and targeted TNCO deliveries. Thus, the two products can be considered equivalent and the reported data can be used interchangeably for both brands." The chemistry and toxicology reviewers examining this amendment to the SE reports reviewed the data provided by CBI with respect to these new tobacco products and the surrogate products, [redacted]

[3] There is an additional basis for overturning an Engineering-related deficiency in the NSE orders issued for SE0002732-2735, and 2740, described in more detail in note 6 below.
[4] Deficiency 1 of the NSE order issued for SE0002734; Deficiency 9 of the NSE order issued for SE0002735.

(b)(5) Deliberative Process Privilege

On appeal, OS reverses its conclusions regarding the sufficiency of CBI's statement regarding the use of surrogate product data. OS advised that CBI's statement in the response to the PFind that the surrogate and new tobacco products have "identical construction" should have been adequate for OS to consider the TNCO data that CBI provided because CBI also stated that the products were manufactured in the same manner and using the same design parameters, and that the only difference between the new and surrogate tobacco products is in terms of brand identifiers. OS examined the TNCO yields of the surrogate product and has determined that the yields are all within the typical analytical variability of the measurement procedure and thus the difference in characteristics do not cause the new tobacco products to raise questions of public health.

I concur with OS's finding that CBI's explanation of the surrogate product's characteristics justifies the examination of the TNCO yields. Because OS has now determined that the difference in characteristics do not cause the new tobacco products to raise different questions of public health, these deficiencies and the associated NSE orders do not stand.[5,6]

(b) (4)

(b) (4)

[redacted]

[5] Deficiency 9 of the NSE order issued for SE0002735 also noted an increase in tar, nicotine, and carbon monoxide (TNCO) yields from the new tobacco product (using TNCO data from the surrogate product in lieu of the new product) compared to the predicate tobacco product. Because the increases were comparable to or less than those reported for the other CBI products reviewed, and because the toxicology review ultimately concluded that the increases for these other CBI products did not raise different questions of public health because they were "likely caused by the inherent variability in the testing as well as the natural variation of the tobacco in the products," the increases in SE0002735 also do not raise different questions of public health. *See* Second Cycle Toxicology Review at 10-12.

[6] The following Engineering deficiencies are also overturned on this basis, in addition to the basis described in the *Engineering Deficiencies* section: Deficiency 3 of the NSE orders issued for SE0002732-2733, 2735, 2740; Deficiency 4 of the NSE order issued for SE0002734.

[7] (b) (4) [redacted]

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

[redacted]

(b)(4), (b)(5) Deliberative Process Privilege

[redacted]

(b)(4), (b)(5) Deliberative Process Privilege

[redacted]

[8] (b)(4)

[redacted]

[9] (b)(4), (b)(5) Deliberative Process Privilege

[redacted]

(b)(4), (b)(5) Deliberative Process Privilege

[redacted]

Conclusion

For the reasons described above, I grant CBI's appeal request. To operationalize this decision, I have directed OS to rescind the NSE orders for SE0002732-2736, and 2739-2740. I further directed OS to issue SE orders for SE0002732, 2734-2736, and 2739-2740. (b) (4)

[redacted]

This decision reflects the conclusion of supervisory review of these appeal requests at the Center level. In accordance with 21 C.F.R. § 10.75, if you are dissatisfied with the decision, you may appeal to the Commissioner of Food and Drugs. If you have any questions regarding this letter, please contact Nathan Hurley, CTP Ombudsman, by email (Nathan.Hurley@fda.hhs.gov) or phone (301-796-3095).

Sincerely,

Shawn L. Fultz -S

Digitally signed by Shawn L. Fultz -S
Date: 2019.04.17 09:32:19 -04'00'

Shawn L. Fultz, MD, JD, MPH
Chief
Economics and Special Projects Branch
Center for Tobacco Products

cc: Matthew Holman, PhD, Director, Office of Science
Mitch Zeller, Center Director
Glen Jones, Deputy Director for Regulatory Science and Management, Office of Science
Cristi Stark, Director, Division of Regulatory Project Management, Office of Science
Ann Simoneau, Director, Office of Compliance and Enforcement

ATTACHMENTS
Attachment A: Rescission letters for SE0002732-2736 and SE0002739-40
Attachment B: SE order letters for SE0002732, SE0002734-36, and SE0002739-40