



FDA Submission Tracking Number (STN): AP0000017
APPEAL GRANTED

January 13, 2017

Gerard J. Roerty, Jr.
Vice President, General Counsel & Secretary
Swedish Match North America, Inc.
1021 East Cary Street, Suite 1600
Richmond, VA 23225

Subject: Swedish Match North America's Request for Supervisory Review of FDA's
November 10, 2015, Not Substantially Equivalent Order for STN: SE0010528
(Appeal STN: AP0000017)

Dear Mr. Roerty:

I have completed the review of your request for supervisory review, received December 22, 2015, under Title 21 of the Code of Federal Regulations (C.F.R.) section 10.75. Swedish Match North America, Inc., (SMNA) requested supervisory review of a Not Substantially Equivalent (NSE) order that the Center for Tobacco Products (CTP) issued on November 10, 2015, regarding STN: SE0010528 ("SE 528") (see Enclosure 1 for your Appeal Request letter and the NSE Order). 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 General Classic Blend Portion White Large not substantially equivalent to its predicate product. As part of this review, I have consulted with senior representatives from OS.

After reviewing all of the information submitted in your appeal, including your supplemental materials received August 24, 2016, and other relevant information as discussed herein, your appeal is granted, and I am directing OS to issue a substantial equivalence (SE) Order for SE 528.¹ I describe below the bases for your appeal and my decision.

Background

On November 10, 2015, OS issued an NSE Order to SMNA for the following STN: SE0010528 ("SE 528") – General Classic Blend Portion White Large. The Substantial Equivalence (SE) Report for this product was filed on June 10, 2014, and referenced General Portion White Large

¹ As noted below, because I am directing OS to issue an SE Order for SE 528, it is not necessary to address all of the issues raised in the appeal.

as its predicate product. In addition to other differences, the characteristics of the new and predicate products differed with respect to product quantity (12 pouches in the new product versus 24 pouches in the predicate product) and package shape (rectangular new can versus round predicate can). OS found that SMNA failed to demonstrate that differences in product quantity and package shape of the new product do not raise different questions of public health as compared to the predicate product.

On December 22, 2015, SMNA submitted an Appeal Request asking that CTP vacate the NSE Order and return the SE Report to OS for review. SMNA argued in its Appeal Request that:

- Changes in packaging and product quantity do not implicate different questions of public health;
- The Tobacco Control Act (TCA) does not provide FDA with authority to consider packaging in the context of SE review;
- Including changes to packaging and product quantity in the SE review was inconsistent with OS's prior guidance;
- The NSE determination's reliance on packaging changes violates the First Amendment;
- The FD&C Act does not permit OS to consider price in reviewing SE Reports; and
- OS failed to conduct a science-based review of the data supporting the SE Report.

SMNA requested a meeting regarding this appeal, and a meeting was held on February 10, 2016. The meeting was attended by Gerry Roerty of SMNA; Ben Haas and John Manthei of Latham & Watkins; Richard Turman, David Ashley, Ella Yeargin, David Portnoy, Mallory Johnson, and Dan Reed of CTP; and Jessica Greenbaum and Laura Vichinsky of the Office of the General Counsel, Department of Health and Human Services.

Section 910(a)(2) of the FD&C Act requires premarket review and marketing authorization before manufacturers can introduce new tobacco products into interstate commerce. One way of obtaining such authorization is by submitting an SE Report to FDA under section 905(j) and obtaining an order under section 910(a)(2) finding that the new tobacco product is: (1) substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007; and (2) in compliance with the requirements of the FD&C Act.

The FD&C Act authorizes FDA to issue a substantial equivalence order when FDA finds that the new tobacco product, when compared to a predicate tobacco product, either: (1) has the same characteristics as the predicate tobacco product; or (2) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by FDA, that demonstrates that it is not appropriate to regulate the product under the requirements for a Premarket Tobacco Application (PMTA) because the new product does not raise different questions of public health. *See* § 910(a)(3).

When submitting an SE Report, the applicant bears the burden of demonstrating that the new and predicate tobacco products are substantially equivalent.

Decision

Upon review of your Appeal Request and the administrative record, I find that the evidence in the record supports a finding of substantial equivalence for SE 528. I describe below the bases for my decision.² Sections 1, 3, and 5 discuss SMNA's arguments regarding SE 528's change in product quantity while sections 2 and 4 discuss SMNA's arguments regarding SE 528's change in the container closure system.

1. **The Evaluation of Whether a Change in Characteristics Raises Different Questions of Public Health Is Not Limited to an Evaluation of "Toxicity or Inherent Health Risks"**

SMNA argues that OS exceeded its authority under the FD&C Act and misconstrued the "different questions of public health" standard in section 910(a)(3)(A)(ii) when OS considered "consumer perception and product appeal" in determining whether SMNA's new tobacco products are substantially equivalent to the predicate tobacco products. SMNA contends that FDA's evaluation of whether the company's new tobacco products raise different questions of public health is "limited to considering science-based evidence related to increased toxicity or inherent health risks of the product to consumers." For the reasons discussed below, I disagree with SMNA's narrow reading of "different questions of public health."

For products like SMNA's General Classic Blend Portion White Large, which has different characteristics than its predicate tobacco product, substantial equivalence is defined to mean that "the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health." *See* FD&C Act § 910(a)(3)(A)(ii). Section 910(a)(3)(A)(ii) does not further specify what types of "public health" issues should be considered, but Congress included findings in the Tobacco Control Act that make clear that the legislation's public health goals included reducing dependence on tobacco:

- "Tobacco use is the foremost preventable cause of premature death in America."
- "The use of tobacco products by the Nation's children is a pediatric disease of considerable proportions that results in new generations of tobacco-dependent children and adults."

²While not addressed in the body of the discussion below, I would also like to note that I disagree with SMNA's assessment that including changes to the container closure system and product quantity in the SE review was inconsistent with OS's prior guidance. As SMNA notes in your Appeal Request, "the SE Guidance does not mention packaging or portion count." However, the guidance also does not expressly exclude those factors from SE review. The SE Guidance does not contain an exhaustive list of all of the types of information that FDA might consider in its evaluation of an SE Report; rather, it is intended to help guide industry by providing examples of the types of information that the Agency might consider when evaluating an SE Report.

- “Because past efforts to restrict advertising and marketing of tobacco products have failed adequately to curb tobacco use by adolescents, comprehensive restrictions on the sale, promotion, and distribution of such products are needed.”
- “Nicotine is an addictive drug.”
- “Tobacco dependence is a chronic disease” and the “the only safe alternative to smoking is cessation”
- “It is in the public interest for Congress to adopt legislation to address the public health crisis created by actions of the tobacco industry.”

See TCA §§ 2(1), (3), (6), (13), (29), (33) & (34). Indeed, Congress stated that the TCA’s “purposes” include “ensur[ing] that the [FDA] has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco” and “promot[ing] cessation to reduce disease risk and the social-costs associated with tobacco-related diseases” TCA §§ 3(2) & (9). As a result, in determining whether a product raises different questions of public health, FDA considers potential impacts on initiation and cessation of tobacco use.

There is nothing in the FD&C Act indicating that the “questions of public health” to be considered in SE determinations are limited to toxicity or “inherent health risks.” Instead, SMNA bases its position that Congress did not grant FDA authority “to consider consumer appeal in evaluating SE applications” on a comparison of the review standards for SE Reports and Premarket Tobacco Applications (PMTAs). For PMTAs, the statute directs FDA to deny an application if the agency finds that “there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health.” § 910(c)(2)(A). To determine whether marketing a tobacco product is appropriate for the protection of “public health,” section 910(c) instructs FDA to consider the “increased or decreased likelihood that” nonusers “will start using” the tobacco product and that “existing users will stop using such products.” See § 910(c)(4). Thus, a product’s potential impact on initiation and cessation of use of the tobacco product is a critical factor in the “appropriate for the protection of the public health” standard for authorization of a PMTA.

SMNA reasons in its Appeal Request that because “Congress explicitly permitted FDA to consider” the likelihood that nonusers will start using a tobacco product and that existing users will stop using when reviewing a PMTA but failed to explicitly list those factors in section 910(a)(3)(A)(ii), “Congress did not grant FDA the authority to consider these factors in reviewing whether modifications cited in an SE Report ‘raise different questions of public health.’” This interpretation ignores the fact that Congress – in addition to not limiting the scope of the “public health” inquiry under section 910(a)(3)(A)(ii) – expressly referred to the PMTA pathway in the SE provision. As noted, Congress defined substantial equivalence to mean that “the information submitted contains information, including clinical data if deemed necessary by the Secretary, ***that demonstrates that it is not appropriate to regulate the product under this section*** because the product does not raise different questions of public health.” See FD&C Act § 910(a)(3)(A)(ii) (emphasis added). The reference to “this section” in the italicized language is a reference to the PMTA pathway, which is found in section 910(c). To determine whether it is “*not appropriate* to regulate” a tobacco product under a PMTA – and therefore it *is appropriate* to regulate the product under the SE pathway – it logically follows that the “public health”

considerations relevant to the PMTA pathway are also relevant to the SE pathway. In other words, because one of the considerations for FDA finding that a product is appropriate for the protection of public health (i.e., the PMTA “standard”) includes the increased or decreased likelihood that existing users will stop using and new users will initiate use of such products, it is reasonable to examine those same considerations under the SE standard to determine whether the differences between the predicate and the new product show that the product should be reviewed under the PMTA pathway.

For all of these reasons, I reject SMNA’s argument that OS exceeded its statutory authority in considering consumer perception and product appeal.

2. The TCA Provides FDA Authority to Review Certain Packaging Changes

SMNA believes that OS erred in reviewing the packaging of the new product, arguing that packaging is distinct from the “tobacco product” and thus not subject to SE review. SMNA also states that FDA’s authority over packaging is found outside the SE provisions and is limited to preventing product adulteration (§ 902) and application of good manufacturing practice to the manufacture of tobacco products (§ 905(e)).

I disagree with these contentions. The subset of packaging that is the container closure system is a component or part of a tobacco product and can be reviewed through the SE process.

As noted above, FDA has the authority to review and authorize new tobacco products before they are introduced into interstate commerce. “New tobacco product” is defined under the FD&C Act as:

(A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or

(B) any modification (including a change in design, *any component, any part*, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

§ 910(a)(1) (emphasis added). In some circumstances, materials can function both as packaging and as a component or part of the tobacco product. In these cases, FDA only examines that distinct subset of packaging materials that is also a component or part of the tobacco product. As defined in 21 C.F.R. § 1143.1, “[c]omponent or part means any software or assembly of materials intended or reasonably expected: (1) To alter or affect the tobacco product’s performance, composition, constituents, or characteristics; or (2) to be used with or for the human consumption of a tobacco product.”³ Therefore, packaging is a component or part where it is intended or reasonably expected to alter or affect the tobacco product’s performance, composition, constituents, or characteristics. As noted above, FDA refers to this subset of

³ The regulation that codified this definition was not effective until August 8, 2016; however, the definition is consistent with OS’s thinking about the types of products that would be components or parts under the definition at the time of the SE review.

packaging as the “container closure system.” As a result, where packaging is a component or part of a tobacco product, evaluation of changes to the packaging is within the scope of the SE review process.

In SE 528, the can holding the snus pouches is the container closure system, which is a component or part of the tobacco product because it is reasonably expected to alter or affect the tobacco product’s performance, composition, constituents, or characteristics. For example, changes in the can for SE 528 are reasonably expected to alter or affect the moisture levels of the tobacco product, which in turn can affect microbial growth in the product, and may affect nicotine absorption and exposure to certain carcinogens.

The container closure system is a component or part of a tobacco product because of its potential to alter or affect the characteristics of the product. Although the container closure system’s impact on the physical characteristics of the product may be relevant in assessing the appeal of a product in some circumstances, I do not believe such a review was warranted here. OS’s SE analysis was based on the change in shape of the package and how that shape change, by itself, might affect the appeal of the product. However, the review did not identify changes to the product’s performance, composition, constituents, or characteristics that could impact the appeal of the product.

Because the concern regarding the shape change in SE 528’s container closure system relied exclusively on an examination of the effect that this particular shape change could have on consumer perception and product appeal, I find that this deficiency should not stand and overturn this basis for the NSE decision.

3. OS Failed to Consider the Evidence Provided by SMNA in Light of the Level of Concern OS Had Regarding the Change in Product Quantity

Before assessing the evidence submitted by SMNA in support of its contention that the differences between this product and its predicate do not raise different questions of public health, it is important to understand the concern that led OS to ask SMNA to submit data showing that the proposed changes in product quantity do not raise different questions of public health. In the SE context, CTP has previously stated – both in guidance and in correspondence regarding the application at issue – that product quantity changes can raise different questions of public health. Such changes can affect consumer harm perceptions, use intentions, and use behavior. Such changes can impact initiation of tobacco use because, for example, smaller product quantities may encourage increased product uptake due to lower barriers to trying the product. Higher quantities can potentially reduce cessation behaviors and increase tobacco product use among current users.

Although changes in product quantity can raise different questions of public health, the Center also recognizes that not all such changes prompt equal level of concern. In the products at issue here, the product quantity decreased from 24 to 12 pouches. The proposed quantity is thus not a novel or “trial size” that appears most likely to have a significant impact on consumer harm perceptions, use intentions, or use behavior. Thus, although I agree that the type of change at issue here *could* raise different questions of public health, the risk appears to be relatively low.

As such, any analysis of the evidence put forth by SMNA in this particular instance should be viewed in the light of that level of concern.

Evidence Submitted by SMNA

SMNA provided several pieces of evidence to support its contention that the reduction in product quantity does not raise different questions of public health. Included in these submissions were the “Premarket Consumer Perception Study,” the (b)(4)⁴ and national sales data.

OS determined that the information SMNA submitted was insufficient to demonstrate that the reduction in product quantity would not cause the new products to raise different questions of public health. In making this finding, OS reviewed the (b)(4) and found that fundamental methodological issues made the findings difficult to interpret and insufficient to support SMNA’s arguments. OS also identified significant deficiencies in the other evidence SMNA submitted.

I agree with OS that the (b)(4) has significant methodological flaws that make it difficult to interpret the data. I also note that although SMNA has argued that the (b)(4) (b)(4) is “robust and scientifically valid,” its Appeal Request did not specifically address the methodological flaws OS identified in that study.

While I acknowledge that methodological flaws in a study can be so significant that no conclusion or evidence can be drawn from it, the flaws identified in the (b)(4) do not seem to prevent *any* interpretation and consideration of the results. Although the study design may prevent me from understanding whether (b)(4)

particular, the study purports to demonstrate that when comparing the 24 count product to the 12 count product, (b)(4)

SMNA also provided market sales data in its SE application.⁵ These data were submitted both in response to the February 5, 2015, Preliminary Finding letter and in August 2016 in response to my invitation to submit updated data during the course of this appeal. The submitted sales data indicate that (b)(4)

As OS noted, these sales data are of limited value: they were (b)(4)

⁴ For clarification purposes, I note that SMNA referred to this study as the “Consumer Study” in its Appeal Request. This decision adopts the name “(b)(4)” used in the NSE Orders to avoid confusion with the “Premarket Consumer Perception Study” that SMNA primarily submitted in support of its Modified Risk Tobacco Product Applications for this same General Snus product among others.

⁵ Although SMNA provided the sales data to support its assertion that the shape changes in the new products do not raise different questions of public health, the data are also relevant to address whether the product quantity change causes the new product to raise different questions of public health.

(b)(4)

However, the sales data do provide some, albeit limited, support for SMNA's position.

SMNA also provided data from its Pre-market Consumer Perception Study conducted in support of its Modified Risk Tobacco Product Applications. As OS notes in its review, (b)(4)

These facts would seem to suggest that, coupled with the information provided above, this particular decrease in product quantity would not likely impact initiation and tobacco use in ways that would raise different questions of public health.

Considering all the evidence provided by SMNA in light of the level of concern regarding this particular change in product quantity, I find that this product does not raise different questions of public health and therefore should have been found substantially equivalent. As I noted above, product quantity changes may raise different questions of public health, but some product quantity changes will raise a lower level of concern than others. For the reasons noted above, I conclude that there is limited evidence of particular concern for the particular product quantity at issue in this SE Report. Consequently, the level of evidence required to demonstrate that this particular product does not raise different questions of public health is substantially less than it would be for products changed in ways that prompt greater levels of public health concern.

Against that backdrop, even though I have concerns about the significant limitations in each type of data submitted by the applicant, considering the available data and information before me, I find that the totality of the evidence submitted by SMNA is sufficient to show that this particular product quantity change does not raise different questions of public health. Therefore, I find that this deficiency should not stand and overturn this basis for the NSE decision.

4. It Is Not Necessary to Address SMNA's Arguments Regarding the First Amendment

SMNA argues that the first deficiency listed in the NSE order (failure to show that the change in shape of the new tobacco product did not raise different questions of public health) violates the First Amendment. Given that, as explained above, I find that the NSE was issued in error and the new product's change in shape (and product quantity) do not

raise different questions of public health, it is not necessary for me to address SMNA's arguments regarding the First Amendment.⁶

5. OS Used Price as a Proxy Measurement for Product Appeal

SMNA also argues that the FDCA does not permit OS to consider price in reviewing SE Reports. Given that, as explain above, I find that the NSE was issued in error and that the change in product quantity (and shape) of the new product do not raise different questions of public health, it is not necessary to address this argument.⁷

Conclusion

For the reasons stated above, I have decided that each of the two bases for the NSE decision should not stand. Therefore, I am granting your Appeal Request. To operationalize this decision, I am directing OS to today rescind the NSE Order for SE 528 (General Classic Blend Portion White Large) and issue an SE Order for that product. These letters are enclosed.

This decision reflects the conclusion of supervisory review of this consolidated appeal request 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 Acting Ombudsman, by email (Nathan.Hurley@fda.hhs.gov) or phone (301-796-9326).

Sincerely,



Richard J. Turman
Deputy Director
Center for Tobacco Products

Enclosures (3):

Appeal Request letter (with Nov. 2015 NSE Order)
NSE Rescission for SE0010528
SE Order for SE0010528

⁶ I read SMNA's appeal to raise a First Amendment argument only with respect to OS's decision as it relates to the shape of the package of the tobacco product. Even if this is not the case, because I am finding that the product is substantially equivalent, it is not necessary to reach the issue of whether the NSE determination's basis on product quantity raises First Amendment concerns.

⁷ While it is true that OS mentioned price in Deficiency 17 of the September 9, 2014, Advice/Information Request letter, I note that OS's primary stated concern was that the reduced number of portions per package could influence consumer perceptions and product appeal. As OS explained in that letter, "providing fewer portions in a single package may reduce barriers to initiation."

Enclosure 1

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SWEDISH MATCH

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DEC 22 2015
BY: CTP/DCC

Gerard J. Roerty, Jr.
Vice President, General Counsel &
Secretary

December 22, 2015

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BY: CTP/MAILROOM

VIA COURIER

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

AP0000017

Re: REQUEST FOR SUPERVISORY REVIEW - SE0010528

Dear Sir or Madam,

Swedish Match North America, Inc. ("SMNA") submits this letter pursuant to 21 C.F.R. § 10.75 to request supervisory review of the Not Substantially Equivalent ("NSE") determination issued by the Food and Drug Administration's ("FDA's") Center for Tobacco Products ("CTP") Office of Science ("OS") on November 10, 2015.¹ Specifically, SMNA requests supervisory review by the Director of CTP of the OS determination that SMNA's submission under Section 905(j) of the Federal Food, Drug and Cosmetic Act ("FDCA") for **General Classic Blend Portion White Large (SE0010528)** "snus" (smokeless tobacco product) (the "SE Report") is not substantially equivalent to its predicate tobacco product because of changes in portion count and packaging shape.

OS based the NSE determination on SMNA's purported failure to provide sufficient information to demonstrate that "consumer perception and product appeal would not be affected" by a change in the number of portions of tobacco in each new package or by the new rectangular package shape. As discussed below, OS erred in denying the SE Report based on concerns related to the packaging and portion count of the tobacco product, and by extension its price, because those factors are not properly before OS during the review of an SE application. OS also failed to articulate a reasonable basis for denying the SE application based on the record evidence. Therefore, SMNA respectfully requests that the NSE determination be vacated and returned to OS for review.

¹ Attachment A.

Swedish Match North America Inc.

| Postal address: | Visiting address: | Phone: | Fax: |
|---------------------------------------|-------------------------------------|--------------|--------------|
| P.O. Box 13297 Richmond, Va. 23225 | 1021 East Cary Street Suite 1800 | 804 787-5177 | 804 255-7094 |

In accordance with 21 C.F.R. § 10.75, this Request for Supervisory Review relies on, and incorporates by reference, the administrative record for SE0010528, which contains all pertinent information related to this submission. SMNA also requests an in-person meeting so that it may have the opportunity to make the case directly to the reviewing authority.

I. BACKGROUND

On June 14, 2014, SMNA submitted the SE Report,² demonstrating that its new tobacco product is substantially equivalent to the predicate tobacco product identified in the submission, General Portion White Large. On September 9, 2014, OS issued an Advice/Information Request letter in response to the SE Report, asking SMNA to provide information related to changes in tobacco blend composition, tobacco particle size, additives, and shelf life compared to the predicate tobacco product. OS also asked SMNA to provide its rationale for (a) a change in the number of portions per package, and (b) a change in the design of the package from a single round container to a rectangular container with a separate compartment for the disposal of used tobacco. OS expressed concern that "...decreases in package sizes from the larger predicate products to...smaller new products affects consumer perception and product appeal. For example, smaller package sizes may reduce barriers to initiation by lowering the price, making the product easier to use, or making the product easier to conceal." Similarly, OS asserted that "fewer portions in a single package may reduce barriers to initiation by lowering the price" and "a new shape of can...may make the product[] more appealing to consumers."

On November 6, 2014, SMNA submitted a comprehensive response to the Advice/Information Request. In its response, SMNA objected to the questions related to the shape of packaging and number of portions per package because, under the FDCA, SE review is not required for labeling and packaging changes that do not impact the characteristics of the consumed tobacco product. As SMNA explained, an interpretation that a change in labeling and packaging presumptively renders a tobacco product a "new tobacco product" subject to SE review under Section 905(j) is inconsistent with the plain language of the Tobacco Control Act ("TCA"). SMNA also observed that that TCA provides FDA with extensive authority over tobacco product labeling and packaging in other parts of the Act. Finally, SMNA noted that FDA's questions regarding the size and shape of packages were inconsistent with prior FDA guidance, including FDA's 17-page *Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products Guidance* ("SE Guidance"), which provided an extensive list of data to be submitted with an SE application. This lengthy list does not include packaging or portion count.

Without waiving those objections, SMNA submitted consumer perception data and market sales data, predominantly drawn from the Company's pending Modified Risk Tobacco

² SMNA submitted SE Reports for ten products on this date, including SE0010528, which is the subject of this correspondence.

Product Application (“MRTPA”) for the same product, to address OS’s concerns. SMNA noted that the new design with lower portion count was (b) (4) (b) (4) which might lessen the product’s appeal compared to the predicate tobacco product. SMNA also indicated that users of the tobacco product might find the smaller package less appealing due to the inconvenience of having to purchase the product more frequently to maintain the same level of use. SMNA provided data demonstrating that its 12- or 15-pouch offerings are consistent with the 6- to 24-pouch range for most suppliers of snus tobacco products to the United States market.

On February 5, 2015, OS issued a Preliminary Finding letter. In addressing SMNA’s response on the decreased portion quantity, OS explained in pertinent part that (b) (4) (b) (4) (b) (4) respectively (b) (4). Thus, a change in a product characteristic, namely the portion quantity, could alter the appeal for non-users by reducing barriers to initiation.” OS therefore requested additional consumer perception and sales and marketing data related to product packaging and portion count.

On March 6, 2015, SMNA submitted a comprehensive response. SMNA reiterated its position that changes to portion count and packaging were not factors that could properly be considered as part of the SE review process. However, to support its response, SMNA also provided the results of a consumer perception study that examined, among other factors, the (b) (4) (b) (4) (the “Consumer Study”). The Consumer Study surveyed (b) (4) (b) (4)

(b) (4) The design of the Consumer Study was consistent with that of the Premarket Consumer Perception Study that SMNA developed – based on extensive discussions with, and input from, CTP – to support the MRTPA for the same product. The Consumer Study showed that (b) (4)

(b) (4) The Consumer Study demonstrated that (b) (4)

(b) (4)

(b) (4) The Consumer Study further demonstrated that (b) (4)

(b) (4) Further, the results of the Consumer Study were consistent with the results of SMNA’s Premarket Consumer Perception Study, which showed that (b) (4)

(b) (4) and market sales data showing a (b) (4) (b) (4)

Despite submission of these data, OS issued the NSE determination on November 10,

2015. OS stated that SMNA failed to show that changes to the size or shape of the packaging for the tobacco product, or the number of portions per package, would not affect consumer perception or product appeal in a manner that would cause the new products to raise different questions about public health. OS faulted SMNA's studies for (b) (4)

(b) (4)

OS also criticized the study for (b) (4)

(b) (4)

(b) (4)

OS noted that SMNA did not indicate if it conducted (b) (4) prior to conducting the Consumer Study, and suggested the study was conducted "ad hoc." In evaluating the Consumer Study, OS rejected SMNA's claim that a (b) (4) OS also declined to credit SMNA's market sales data and suggested that (b) (4)

(b) (4) More generally, the NSE determination did not include any information to suggest that the changes in the new tobacco products were reasonably likely to "increase product appeal and/or reduce barriers to initiation."

II. ANALYSIS

A. The TCA Does Not Provide FDA with Authority to Consider Packaging in the Context of SE Review

Under Section 910(a)(3) of the FDCA, in order to find that a new tobacco product is substantially equivalent to a predicate tobacco product that has different characteristics, FDA must find that the information submitted by the applicant demonstrates that the product does not raise different questions of public health. SE Reports must provide sufficient information to enable FDA to determine whether the new tobacco product is substantially equivalent to an appropriate predicate product within the meaning of Section 910(a)(3).³ In addition, FDA may request additional information or data for products with different characteristics that the applicant believes do not raise different questions of public health, if needed to make a substantial equivalence determination.⁴ None of the reasons for an NSE determination can survive review in this instance.

As an initial matter, the FDCA's substantial equivalence provisions do not apply to the packaging of a tobacco product or the number of portions per package, and OS erred in relying on those factors in denying the SE application. FDA apparently reads the phrase "any part...of a tobacco product" to include packaging in asserting authority over the different package shape

³ FDA, *Guidance for Industry and FDA Staff: Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products* (2011), at 7.

⁴ *Id.* at 12.

described in the SE Report. The statute, however, defines “tobacco product” as “any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product.” That definition clearly does not contemplate packaging, as packaging is neither a consumable tobacco product, made or derived from tobacco, nor a “component part or accessory” of such a product. Therefore, packaging is not a consumable product or a part of that consumable product that would be subject to SE review. Indeed, in its most recent guidance document on SE requirements, FDA clearly distinguishes between a tobacco product and its package by confirming that a “package” is “the pack, box, carton, container, or wrapping (such as cellophane), *in which a tobacco product is sold to consumers.*”⁵ (emphasis added).

This plain reading is supported by neighboring statutory provisions. For example, in Section 900, the FDCA defines a package as a “pack, box, carton, or container of any kind...in which a tobacco product is offered for sale...”⁶ This definition establishes that a “tobacco product” is something that is placed *within* a package or container, not something that already includes packaging. Section 900 defines a counterfeit tobacco product as “a tobacco product (or the container or labeling of such a product) that, without authorization, bears the trademark, trade name, or other identifying mark...of a tobacco product...” Similarly, Section 301(qq)(2) of the Act states that persons are prohibited from “[m]aking, selling, disposing of, or keeping in possession...[any item] that is designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another...upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.” If FDA were correct in its interpretation that the packaging or labeling of a tobacco product is part of the tobacco product, the words “or container or labeling thereof” in this provision would be superfluous. It is clear from the plain language of the statute that the container, packaging, or label of a tobacco product is not part of the tobacco product itself, as FDA itself acknowledged in its most recent SE guidance document.

Other provisions of the FDCA confirm that FDA does not have authority to review product packaging through the SE review process. Congress has given FDA authority over packaging of tobacco products, but it is not the type of authority that FDA seeks to assert in the NSE determination. Section 902 of the FDCA gives FDA authority to ensure that the packaging itself is not contaminated or made with materials that could impact public health. Specifically, Section 902 states that a tobacco product shall be considered adulterated if “it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.” It will also be deemed adulterated if “its package is composed, in whole or in part, of any poisonous or deleterious

⁵ FDA, *Guidance for Industry: Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 2)* (2015), at 16 n. 18.

⁶ 21 U.S.C. § 387(13).

substance which may render the contents injurious to health,”⁷ or if “the methods used in, or the facilities or controls used for, its manufacture, packing, or storage are not in conformity with applicable requirements under section 906(e)(1) [Good Manufacturing Practices, or GMPs].”⁸ Accordingly, Section 902 grants FDA multiple sources of authority over tobacco product packaging, but that authority does not include review of packaging content or configuration pursuant to SE review provisions under Section 905(j).

Notably, the Act’s language on manufacturing practices is nearly identical to the statutory text in Section 520(f) of the FDCA, which establishes GMPs in for medical devices.⁹ FDA’s guidance on *Deciding When to Submit a 510(k) for a Change to an Existing Device* states that “changes in device packaging...of a device do not result in the need for a new 510(k)”—the analogous provision to SE review for tobacco products.¹⁰ Rather, “such changes are properly within the scope of GMPs.” Likewise, FDA’s tool to regulate tobacco product packaging is through GMPs, not substantial equivalence. FDA’s long-standing guidance interpreting the FDCA’s analogous GMP provisions applicable to medical devices as encompassing the packaging changes is very strong evidence that Congress intended the nearly identical language in the tobacco portion of the statute to be interpreted the same way.

B. Changes in Packaging and Portion Count Do Not Implicate Different Questions of Public Health

In attempting to apply the statutory factors, FDA also misconstrued the “different questions of public health” standard in denying the SE applications based on packaging configuration or portion count. To the extent FDA may consider public health concerns during the SE review process, that authority is limited to considering science-based evidence related to increased toxicity or inherent health risks to consumers. The “different questions” relate to the composition of the tobacco product itself and not external factors like consumer appeal or changes in the market. There is no grant of authority in the TCA that would allow FDA to consider consumer appeal in evaluating SE applications. By comparison, in reviewing whether a new tobacco product submitted under a Premarket Tobacco Product Application (“PMTA”) is “appropriate for the protection of the public health,” Congress directed FDA to consider “the increased or decreased likelihood that existing users of tobacco products will stop using such products; and the increased or decreased likelihood that those who do not user tobacco products will start using such products.”¹¹ Similarly, in the FDCA’s provisions governing

⁷ 21 U.S.C. § 387b(2)-(3).

⁸ *Id.* § 387b(7).

⁹ 21 U.S.C. § 360j(f).

¹⁰ FDA, *Deciding When to Submit a 510(k) for a Change to an Existing Device* (1997), at 16.

¹¹ FDCA § 910(c)(4)(A)-(B) (21 U.S.C. § 387j(c)(4)(A)-(B)).

modified risk tobacco products (“MRTPs”), Congress explicitly permitted FDA to consider these same factors in determining whether a proposed modified risk tobacco product would “benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.”¹² In contrast, Congress did not grant FDA the authority to consider these factors in reviewing whether modifications cited in an SE Report “raise different questions of public health,” a review standard different than that applied to PMTAs and MRTPs. As such, in reviewing the SE Report, FDA was limited to reviewing scientific evidence related to the composition and toxicology of the tobacco product itself. As it stands, FDA’s treatment of these SE applications suggests FDA will only approve products through the SE process if they are *less* appealing than their predicate products. That approach is wholly inconsistent with the statutory goals of the SE review process, namely providing a streamlined review process to substantially equivalent products solely to ensure that there is no discernable change in the toxicity of the products.

C. Including Changes to Packaging and Portion Count in the SE Review Was Inconsistent with OS’s Prior Guidance

FDA’s consideration of packaging and portion count is inconsistent with its prior guidance and FDA failed to articulate a reasonable explanation for the change. In its 2011 *SE Guidance*, FDA provided a list of “all product characteristics” to be considered in the substantial equivalence evaluation, including “materials, ingredients, design, [and] composition.”¹³ However, the *SE Guidance* does not mention packaging or portion count as a data point that should be considered in evaluating an SE application. Additionally, Section 904 requires manufacturers to submit “a listing of all ingredients...that are...added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product.”¹⁴ FDA, however, previously interpreted Section 904 to apply to packages only when the manufacturer knows or believes that the additional ingredient will be consumed and otherwise exempts from review those tobacco products where the only change is in the packaging. FDA has not articulated a reason for this abrupt change to its SE review process, beyond claiming in its most recent SE guidance document (issued in 2015) that a change in product quantity results in a change in product characteristics due to differences in the amounts of ingredients, materials, or other features. However, the FDCA clearly reflects the intent that SE review be limited to the characteristics of a tobacco product, not the number of product or portions included within a package. Otherwise, FDA would presumably subject consumer loyalty programs, such as “buy-one, get one free” packages of multiple products sold as a single unit, or a manufacturer’s sale of cartons of

¹² *Id.* § 911(g) (21 U.S.C. § 387k(g)).

¹³ FDA, *Guidance for Industry and FDA Staff: Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products* (2011), at 7.

¹⁴ 21 U.S.C. § 387d(a)(1).

tobacco products in addition to single packs, as actions subject to premarket review. FDA has not done so to date.

D. The NSE Determination's Reliance on Packaging Changes Violates the First Amendment

FDA's efforts to regulate SMNA's packaging decisions through the SE review process infringes on SMNA's commercial speech. Product labels and labeling constitute speech protected under the First Amendment and the Supreme Court has recognized that "so long as the sale and use of tobacco is lawful for adults, the tobacco industry has a protected interest in communicating information about its products and adult consumers have an interest in receiving that information." *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 571 (2001); *see also Rubin v. Coors Brewing Co.*, 514 U.S. 476, 481-82 (1995) (recognizing that "information on beer labels" constitutes protected speech). Packaging sizes and configuration are part of SMNA's labeling and advertising scheme protected under the First Amendment and FDA "bears the burden of justifying its attempt to restrict [that] commercial speech." *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1218 (D.C. Cir. 2012). Here, OS failed to identify a substantial government interest that would be protected by regulating labeling and packaging through the SE process or identify any evidence showing that regulating those characteristics would directly advance that interest. *Central Hudson Gas and Elec. Corp. v. Public Service Comm'n*, 447 U.S. 557, 564 (1980) (requiring also that the government's efforts are "not more extensive than is necessary to serve that interest"). Vague concerns about a change in perception are not enough. Therefore, FDA's efforts to control SMNA's labeling and packaging decisions is an unconstitutional infringement on SMNA's commercial speech.

E. The FDCA Does Not Permit OS to Consider Price in Reviewing SE Reports

OS also erred in injecting the question of price into a determination of whether the new tobacco product is the substantial equivalent of its predicate tobacco product. There is nothing in the statute or FDA guidance to support the position that a substantial equivalence examination of the consumable tobacco product itself should, or could, take into account any related changes in price. Indeed, FDA has no authority to regulate price more generally. There is no broad authority for price regulation either in the FDCA or in the relevant provisions of the Code of Federal Regulations and nothing to suggest that price is a factor that FDA may consider in product review or approval. FDA only has authority to regulate overall costs when Congress explicitly grants that authority in limited circumstances. *See, e.g.*, 21 U.S.C. § 360j(m)(3) (instructing FDA that manufacturers qualifying for the "investigational devices exemption" can only recover the "costs of manufacture, research, development, and handling"); 21 C.F.R. §§ 812.2, 812.7 (implementing the statute). By contrast, there is *no* congressional grant for regulating the price of tobacco products. There are also some reporting provisions that require certain applications to FDA to include the price of the drug or device, but nothing in these provisions allows FDA to *regulate* price or to use price as a factor in

reviewing a premarket submission. *See, e.g.*, 21 C.F.R. § 316.21(c)(6)(ii); 21 C.F.R. § 9.205(b)(1)(ii)(c). It is clear from the absence of price-regulating authority in the TCA that FDA does not have the jurisdiction to set prices. *Cf. Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence, R.I.*, 731 F.3d 71, 81 (1st Cir. 2013) (holding "price regulations" on tobacco products *not* preempted by federal law). Moreover, FDA has stated that it does not have the authority to regulate the price of drugs – presumably this applies to medical devices and tobacco products, too.¹⁵

F. OS Failed to Conduct a Science-Based Review of the Data Supporting the SE Report

Even if OS could have considered consumer perception in its SE review, OS failed to do so in this case. OS's NSE determination is unsupported by any evidence in the record. Indeed, rather than conducting a science-based review of the data submitted in support of SMNA's SE submissions, OS simply dismissed the data based on methodological concerns. SMNA conducted a robust consumer perception study to address OS's concerns relating to the impact of the packaging changes and portion counts. (b) (4)

(b) (4)

(b) (4)

While, as OS noted, the study did not (b) (4)

(b) (4)

The results of the Consumer Study showed that the packaging changes and portion count had no significant impact on (b) (4)

(b) (4)

(b) (4)

While any consumer perception study can be subject to post hoc methodological criticism, the fact remains that SMNA conducted a robust and scientifically valid study that overwhelmingly refutes OS's concerns related to consumer preference. There is no evidence that OS considered the merits of the Consumer Study. Rather than simply dismissing the

¹⁵ See FDA, Opinion Letter (July 2, 2004) 2, available at <http://www.fda.gov/ohrms/dockets/dailys/04/july04/070704/04p-0075-pdn0001.pdf>.

results of the Consumer Study, OS should have conducted a rigorous review based on the weight of the scientific evidence as a whole and in light of the consistent supporting data from the Premarketing Consumer Perception Study and marketing survey. OS erred in failing to base its NSE determination on the scientific evidence in support of SMNA's SE applications.

IV. CONCLUSION

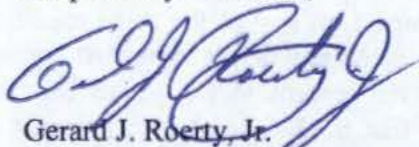
It is clear under FDA law and policy that a NSE determination on a report submitted under Section 905(j) is a final agency action that brings FDA's review of the new tobacco product to a close. OS offered no "reasonable explanation" when it simply disregarded, without comment, SMNA's objections to the request for evidence related to changes in packaging, including the impact of that change on price. OS's actions fall outside the proper realm of agency practice, and SMNA has been disadvantaged as a result. Further, OS's determination that the new tobacco product is not substantially equivalent to the predicate tobacco product because of changes to the shape of the package and number of portions per package is unsupported by the administrative record, and FDA's inquiry fell well outside the scope of its substantial equivalence review. Therefore, OS erred in reaching beyond the scope of substantial equivalence review to deny SMNA's application due to changes in the packaging and number of portions per package. In light of the foregoing, SMNA respectfully requests that the Director of CTP vacate the NSE determination and return the SE application to OS for review.

(b) (4)

(b) (4)

We appreciate your attention to this matter and request an opportunity to meet with the Director of CTP to further discuss the issues. In the meantime, please do not hesitate to contact the undersigned at (804) 787-5177 or Gerry.Roerty@smna.com if you have any questions or concerns.

Respectfully submitted,



Gerard J. Roerty, Jr.
Vice President, General Counsel & Secretary
Swedish Match North America, Inc.

cc: Mitchell R. Zeller, J.D. (HF-13)
Director, Center for Tobacco Products
Food and Drug Administration
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

David L. Ashley, Ph.D.
RADM, U.S. Public Health Service
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Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002



November 10, 2015

NOT SUBSTANTIALLY EQUIVALENT

Swedish Match North America Inc.
Attention: Gerard J. Roerty, Jr., Vice President, General Counsel & Secretary
Two James Center
1021 East Cary Street Suite 1600
Richmond, VA 23219

FDA Submission Tracking Number (STN): SE0010528

Dear Mr. Roerty:

We have completed our review of your Report Preceding Introduction of Certain Substantially Equivalent Products into Interstate Commerce (SE Report), submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the following tobacco product:

New Tobacco Product

| | |
|--|---|
| Tobacco Product Manufacturer: | Swedish Match North America, Inc. |
| Tobacco Product Name¹: | General Classic Blend Portion White Large |
| Tobacco Product Category: | Smokeless Tobacco |
| Tobacco Product Sub-Category: | Portioned Snus |
| Package Type: | Plastic Can |
| Package Quantity: | 10.8 g |
| Portion Count: | 12 pouches |
| Characterizing Flavor: | None |
| Portion Mass: | 900 mg |
| Portion Length: | 34 mm |
| Portion Width: | 14 mm |
| Portion Thickness: | 5 mm |
| Tobacco Cut Size²: | (b)(4) |

¹ Brand/sub-brand or other commercial name used in commercial distribution

² The applicant provided (b)(4) buckets to characterize the tobacco cut size. Therefore, the tobacco cut size cannot be represented with a single size value and corresponding range limit.

We have completed the review of your SE Report and have determined that it does not establish that the new tobacco product specified is substantially equivalent to the following predicate tobacco product:

Predicate Tobacco Product

| | |
|--|-----------------------------------|
| Tobacco Product Manufacturer: | Swedish Match North America, Inc. |
| Tobacco Product Name³: | General Portion White Large |
| Tobacco Product Category: | Smokeless Tobacco |
| Tobacco Product Sub-Category: | Portioned Snus |
| Package Type: | Plastic Can |
| Package Quantity: | 24 g |
| Portion Count: | 24 pouches |
| Characterizing Flavor: | None |
| Portion Mass: | 1000 mg |
| Portion Length: | 34 mm |
| Portion Width: | 18 mm |
| Portion Thickness: | 5.5 mm |
| Tobacco Cut Size⁴: | (b)(4) |

We have described below our basis for this determination.

1. Your SE Report indicates that the portion count is decreased from 24 portions in the predicate tobacco product to 15 portions in the new tobacco product (i.e., decreased 38%). Your SE Report includes the following research data and findings to support your position that consumer perception and product appeal would not be affected by the decreased portion count in a manner that would cause the new tobacco product to raise different questions of public health:

- Question 41 of the Premarket Consumer Perception Study that you conducted in support of your corresponding MRTPAs
- Consumer research that you conducted on (b)(4) referred to as the (b)(4)”

The submitted studies are insufficient to demonstrate that changes in portion count do not influence consumer perception, increase product appeal, and/or reduce barriers to initiation, particularly among non-users.

³ Brand/sub-brand or other commercial name used in commercial distribution

⁴ The applicant provided (b)(4) buckets to characterize the tobacco cut size. Therefore, the tobacco cut size cannot be represented with a single size value and corresponding range limit.

Premarket Consumer Perception Study

You provide data from the *Premarket Consumer Perception Study* (b)(4)

You argue that the data support the conclusion that (b)(4)

||
You do not provide reasons or justification (b)(4)

And, you did not specifically address why (b)(4)

does not cause the new tobacco product to raise different questions of public health.

(b)(4)

The (b)(4) has the following study design and methodological issues that prevent FDA from fully evaluating the study:

(b)(4)

(b)(4)


(b)(4)



(b)(4) The ambiguity (b)(4) (b)(4) may lead to (b)(4) error, making study findings difficult to interpret.

Regarding study measures, it does not appear that they were validated prior to conducting the study. There are limitations with the measures used in this study,

(b)(4)



Therefore, there is no basis for establishing the validity, reliability, or generalizability of the study measures.

2. Your SE Report indicates that the package shapes of the new and predicate tobacco products are different (i.e., round vs. rectangular). Your SE Report includes the following research data and findings to support your position that consumer perception and product appeal would not be affected by the package shape change in a manner that would cause the new tobacco product to raise different questions of public health:

- Market sales data (b)(4)
- Consumer research (b)(4)

The submitted studies are insufficient to demonstrate that changes in package shape do not influence consumer perception, increase product appeal, and/or reduce barriers to initiation.

Market Sales Data

Your SE Report includes (b)(4) market sales data showing (b)(4). However, there are difficulties in drawing causal inferences from the provided data due to the (b)(4). The simultaneous changes (b)(4) prevents us from drawing a conclusion about the impact of each change on (b)(4). Furthermore, you did not conduct (b)(4) analysis of the sales data to evaluate (b)(4), further limiting that ability to draw conclusions of causation (or even correlation). Lastly, some of the market sales data seemingly contradict your argument (b)(4) (see Attachment 7A, tabs (b)(4) of your March 2015 amendment).

(b)(4)

As explained in Deficiency 1 above, there are study designs and methodological issues with this study that make it difficult to fully evaluate the study results. Therefore, this study is inadequate to demonstrate that changes in package shape do not influence consumer perception, increase product appeal, and/or reduce barriers to initiation.

You have failed to provide sufficient information to support a finding of substantial equivalence; therefore, we are issuing an order finding that this new tobacco product is not substantially equivalent to an appropriate predicate tobacco product. You cannot distribute, import, sell, market, or promote this product in the United States. Doing so is a prohibited act under section 301(a) of the FD&C Act, the violation of which could result in enforcement action by FDA.

If you wish to request supervisory review of this decision under 21 CFR 10.75, please submit the request via the FDA Electronic Submission Gateway (www.fda.gov/esg) using eSubmitter, or mail to:

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

We request that your package be sent as a single submission with a cover letter that includes the following text in your subject line: **REQUEST FOR SUPERVISORY REVIEW for SE0010528**. In addition, we request that your package identify each basis for the request and contain all information on which you wish your request to be based; it may not contain any new data or analysis that was not part of your SE Report.

You may not legally market the new tobacco product described in this SE Report unless (1) FDA issues an order finding the product to be exempt from the requirements of substantial equivalence and you make the required submission under section 905(j)(1)(A)(ii) of the FD&C Act, (2) FDA issues an order finding the product substantially equivalent to a predicate tobacco product (section 910(a)(2)(A) of the FD&C Act), OR (3) FDA issues an order authorizing introduction or delivery for introduction into interstate commerce under a premarket tobacco application (section 910(c)(1)(A) of the FD&C Act).

See the following website for additional information on these three pathways:
<http://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/NewTobaccoProductReviewandEvaluation/default.htm>.

If you have any questions, please contact Cecilia Robinson, Regulatory Health Project Manager, at (240) 402-5881.

Sincerely,

Digitally signed by David Ashley -S
Date: 2015.11.10 06:10:02 -05'00'

David L. Ashley, Ph.D.
RADM, U.S. Public Health Service
Director, Office of Science
Center for Tobacco Products

Enclosure 2



January 13, 2017

RESCISSION OF NOT SUBSTANTIALLY EQUIVALENT ORDER

Swedish Match North America, Inc.
Attention: Gerard J. Roerty, Jr., Vice President,
General Counsel & Secretary
Two James Center
1021 East Cary Street Suite 1600
Richmond, VA 23219
via Certified Mail or UPS

FDA Submission Tracking Number (STN): SE0010528

Dear Mr. Roerty:

This letter is in reference to your Report Preceding Introduction of Certain Substantially Equivalent Products into Interstate Commerce (SE Report), for General Classic Blend Portion White Large (SE0010528), submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

On November 10, 2015, you received a determination that your new tobacco product was not substantially equivalent to a tobacco product which was commercially marketed in the United States as of February 15, 2007. On December 22, 2015, you submitted a request for supervisory review under 21 C.F.R. § 10.75.

On January 13, 2017, CTP's Office of the Center Director issued its decision on your request for supervisory review. The decision overturns two of the bases that supported the November 10, 2015, NSE Order: (1) a portion count reduction from 24 portions in the predicate tobacco product to 12 portions in the new tobacco product (i.e., decreased by 50%), and (2) a difference in the package shapes of the new and predicate tobacco products (i.e., round vs. rectangular). Because no deficiencies remain, an SE Order will issue concurrently with this letter.

Accordingly, this letter rescinds your November 10, 2015, NSE order for the following tobacco product:

New Tobacco Product

| | |
|--|---|
| Tobacco Product Manufacturer: | Swedish Match North America, Inc. |
| Tobacco Product Name¹: | General Classic Blend Portion White Large |

¹ Brand/sub-brand or other commercial name used in commercial distribution

| | |
|--------------------------------------|-------------------|
| Tobacco Product Category: | Smokeless Tobacco |
| Tobacco Product Sub-Category: | Portioned Snus |
| Package Type: | Plastic Can |
| Package Quantity: | 10.8 g |
| Portion Count: | 12 pouches |
| Characterizing Flavor: | None |
| Portion Mass: | 900 mg |
| Portion Length: | 34 mm |
| Portion Width: | 14 mm |
| Portion Thickness: | 5 mm |
| Tobacco Cut Size² | (b)(4) |

This is a class of actions that ordinarily would be categorically excluded. There are no extraordinary circumstances that exist which requires preparation of an environmental assessment or an environmental impact statement (see 21 CFR 25.35(c)).

We encourage you to submit all regulatory correspondence electronically via the CTP Portal (<http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm>)³ using eSubmitter (<http://www.fda.gov/ForIndustry/FDAeSubmitter>). Alternatively, submissions may be mailed to:

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

The CTP Portal and FDA Electronic Submission Gateway (ESG) are both generally available 24 hours a day, seven days a week. Submissions delivered to DCC by couriers or physical mail will be considered timely if received during delivery hours on or before the due date (see <http://www.fda.gov/tobaccoproducts/aboutctp/contactus/default.htm>); if the due date falls on a weekend or holiday the delivery must be received on the prior business day. We are unable to accept regulatory submissions by e-mail.

² The applicant provided (b)(4) buckets to characterize the tobacco cut size. Therefore, the tobacco cut size cannot be represented with a single size value and corresponding range limit.

³ The FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.

If you have any questions, please contact Cecilia Robinson, Regulatory Health Project Manager, at (240) 402-5881.

Sincerely,

Digitally signed by David Ashley -S

Date: 2017.01.13 11:32:03 -05'00'

David L. Ashley, Ph.D.

RADM (Ret.), U.S. Public Health Service

Director, Office of Science

Center for Tobacco Products

Enclosure 3



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

January 13, 2017

SUBSTANTIALLY EQUIVALENT

Swedish Match North America, Inc.
Attention: Gerard J. Roerty, Jr., Vice President,
General Counsel & Secretary
Two James Center
1021 East Cary Street Suite 1600
Richmond, VA 23219
via Certified Mail or UPS

FDA Submission Tracking Number (STN): SE0010528

Dear Mr. Roerty:

This letter is in reference to your Report Preceding Introduction of Certain Substantially Equivalent Products into Interstate Commerce (SE Report), for General Classic Blend Portion White Large (SE0010528), submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

On November 10, 2015, you received a determination that your new tobacco product was not substantially equivalent to a tobacco product which was commercially marketed in the United States as of February 15, 2007. On December 22, 2015, you submitted a request for supervisory review under 21 C.F.R. § 10.75.

On January 13, 2017, CTP's Office of the Center Director issued its decision on your request for supervisory review. The decision letter directed the Office of Science to rescind the November 10, 2015, NSE Order and to issue an SE Order in accordance with the outcome of the decision for the following tobacco product:

New Tobacco Product

| | |
|--|---|
| Tobacco Product Manufacturer: | Swedish Match North America, Inc. |
| Tobacco Product Name¹: | General Classic Blend Portion White Large |
| Tobacco Product Category: | Smokeless Tobacco |
| Tobacco Product Sub-Category: | Portioned Snus |
| Package Type: | Plastic Can |

¹ Brand/sub-brand or other commercial name used in commercial distribution

| | |
|-------------------------------------|------------|
| Package Quantity: | 10.8 g |
| Portion Count: | 12 pouches |
| Characterizing Flavor: | None |
| Portion Mass: | 900 mg |
| Portion Length: | 34 mm |
| Portion Width: | 14 mm |
| Portion Thickness: | 5 mm |
| Tobacco Cut Size² | (b)(4) |

Based on our re-review of your SE Report, we find the new tobacco product specified above is in compliance with the requirements of the FD&C Act and substantially equivalent to the following tobacco product, which was commercially marketed in the United States as of February 15, 2007:

Predicate Tobacco Product

| | |
|--|-----------------------------------|
| Tobacco Product Manufacturer: | Swedish Match North America, Inc. |
| Tobacco Product Name³: | General Portion White Large |
| Tobacco Product Category: | Smokeless Tobacco |
| Tobacco Product Sub-Category: | Portioned Snus |
| Package Type: | Plastic Can |
| Package Quantity: | 24 g |
| Portion Count: | 24 pouches |
| Characterizing Flavor: | None |
| Portion Mass: | 1000 mg |
| Portion Length: | 34 mm |
| Portion Width: | 18 mm |
| Portion Thickness: | 5.5 mm |
| Tobacco Cut Size⁴: | (b)(4) |

Under the provisions of section 910 and 905(j) of the FD&C Act, you may introduce or deliver for introduction into interstate commerce the new tobacco product specified above.

² The applicant provided (b)(4) buckets to characterize the tobacco cut size. Therefore, the tobacco cut size cannot be represented with a single size value and corresponding range limit.

³ Brand/sub-brand or other commercial name used in commercial distribution

⁴ The applicant provided (b)(4) buckets to characterize the tobacco cut size. Therefore, the tobacco cut size cannot be represented with a single size value and corresponding range limit.

To fulfill the provisions of section 910(a)(4) of the FD&C Act, you submitted a health information summary in your SE Report. No later than 30 days from the date of this letter, we will make your summary available to the public.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

It is important to note our finding of substantial equivalence for your new tobacco product specified above to an appropriate predicate tobacco product permits marketing of your new tobacco product. Our finding does not mean FDA “approved” the new tobacco product specified above; therefore, you may not promote or in any way represent the new tobacco product specified above, or its labeling, as being “approved” by FDA. See Section 301(tt) of the FD&C Act.

The finding that your product is substantially equivalent to the predicate product is based upon the information you provided in your SE Report and the standards contained in the FD&C Act, Section 910(a)(3). This marketing order is subject to reconsideration, with notice to the manufacturer, and rescission to the extent authorized by law.

We remind you that all regulated tobacco products, including the new tobacco product specified above, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also labeling and advertising requirements with which you must comply. It is your responsibility to ensure the tobacco product specified above complies with all applicable statutory and regulatory requirements, including those which may be forthcoming. FDA will monitor your compliance with these applicable statutes and regulations.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at <http://www.fda.gov/TobaccoProducts>. You may also obtain information by contacting FDA’s Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

We encourage you to submit all regulatory correspondence electronically via the CTP Portal (<http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm>)⁵ using eSubmitter (<http://www.fda.gov/ForIndustry/FDAeSubmitter>). Alternatively, submissions may be mailed to:

⁵ The FDA’s Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.

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

The CTP Portal and FDA Electronic Submission Gateway (ESG) are both generally available 24 hours a day, seven days a week. Submissions delivered to DCC by couriers or physical mail will be considered timely if received during delivery hours on or before the due date (see <http://www.fda.gov/tobaccoproducts/aboutctp/contactus/default.htm>); if the due date falls on a weekend or holiday the delivery must be received on the prior business day. We are unable to accept regulatory submissions by e-mail.

If you have any questions, please contact Cecilia Robinson, Regulatory Health Project Manager, at (240) 402-5881.

Sincerely,

Digitally signed by David Ashley -S

Date: 2017.01.13 11:31:21 -05'00'

David L. Ashley, Ph.D.

RADM (Ret.), U.S. Public Health Service

Director, Office of Science

Center for Tobacco Products