Technical Project Lead (TPL) Memorandum: SE Report SE0004021

SE0004021: Oliver Twist Multipack, Chewing Tobacco Bits	
Package Size	2 grams (0.5 grams of each flavor: Original, Tropical, Sunberry, and Wintergreen)
Package Type	Paper Envelope (Containing 4 Individual Aluminum Packages)
Applicant	House of Oliver Twist A/S
Report Type	Regular
Product Category	Smokeless tobacco product
Product Sub-Category	Chewing tobacco bits
Recommendation	
Issue a Substantial Equivalence (SE) order	

Technical Project Lead (TPL):

Digitally signed by Matthew R. Holman -S
Date: 2014.06.20 16:38:52 -04'00'

Matthew R. Holman, Ph.D.
Director
Division of Product Science

Signatory Decision:

☒ Concur with TPL recommendation and basis of recommendation

☐ Concur with TPL recommendation with additional comments (see separate memo)

☐ Do not concur with TPL recommendation (see separate memo)

Digitally signed by David Ashley -S
Date: 2014.06.20 17:15:30 -04'00'

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

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCT

The applicant submitted the following predicate tobacco product:

Table 1. Predicate Tobacco Product

Oliver Twist Multi Pack (SE0004021)	
Product Name	Oliver Twist Multi Pack[1]
Package Size	3 grams

The predicate tobacco product is manufactured by House of Oliver Twist A/S. They are smokeless tobacco products, chewing tobacco bits, sold in pouches within a plastic container.

1.2. REGULATORY ACTIVITY RELATED TO THIS MEMO

The applicant submitted the original SE Report listed in Table 2 of this memo. FDA sent the applicant administrative advice and information request letter (A/I letter) for this SE Report. In response, the applicant submitted an amendment to the original SE Report (see Table 2). Following our review of the original and amended SE Report, we sent a scientific A/I letter to the applicant in March 2013. The applicant responded to the scientific A/I letter by amending its SE Report (see Table 2). Following our review of the scientific A/I letter, we sent a Preliminary Finding letter to the applicant in December 2013. The applicant responded to the Preliminary Finding letter by amending its SE Report (see Table 2). A TPL memo was filed by me on May 7, 2014, for this SE Report [redacted]. After the TPL memo was filed, it was discovered that the standalone grandfathered review referenced in the SE Report referred to a predicate tobacco product that is a 6-flavor multipack while the predicate tobacco product identified in the SE Report is a 4-flavor multipack. After FDA discussion with the applicant, the applicant submitted amendment SE0010503 revising the predicate tobacco product to the 6-flavor multipack. Therefore, this memo references the 6-flavor multipack predicate tobacco product.

[1] This product contains 6 individual products, each having a net weight of 0.5 grams. The individual products each have one of the following flavors: original, wintergreen, tropical, sunberry, mint, and citrus.

Table 2. SE Reports and Amendments

Product Name	SE Report	Amendments
Oliver Twist Multipack, Chewing Tobacco Bits	SE0004021	SE0004560 SE0008753 SE0010106 SE0010121 SE0010131 SE0010287 SE0010326 SE0010503

1.3. SCOPE OF MEMO

This memo captures all administrative, compliance, and scientific reviews completed for SE0004021. This memo supersedes the TPL memo filed by me on May 7, 2014 (see section 1.2 of this memo).

1.4. KEY DIFFERENCES BETWEEN NEW AND PREDICATE TOBACCO PRODUCTS

The new tobacco products have the following key difference compared to the corresponding predicate tobacco products:

(b) (4)

Removal of two chewing tobacco bit flavors: mint and citrus

2. ADMINISTRATIVE REVIEW

Administrative completeness reviews were completed by Sarah Lee, M.P.H. on February 17, 2012, and Idara Udoh on May 1, 2012. The final administrative completeness review concludes that this SE Report is administratively incomplete. However, a memorandum by Anne Radway on May 7, 2014, concluded this SE Report is administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review dated February 15, 2013, to determine whether the applicant established that the predicate tobacco product is a grandfathered product (i.e., was commercially marketed as of February 15, 2007). The OCE review concludes that the predicate tobacco product is an eligible predicate tobacco product, as the applicant has established that the predicate tobacco product is grandfathered.

The Office of Compliance and Enforcement (OCE) also completed a review to determine whether the new tobacco product is in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act), as required by section 905(j)(1)(A)(i) of the FD&C Act. The OCE review dated June 6, 2014, concludes that the new tobacco product is in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

Scientific reviews were completed by the Office of Science (OS) for the following disciplines. It should be noted that the scientific reviews evaluated the new tobacco product in comparison to the predicate tobacco product identified in this memo without the mint and citrus bits (i.e., the 4-flavor multipack instead of the 6-flavor multipack) (see section 1.2 of this memo). I have reviewed all of the information in the administrative record to date and determined that the conclusions in the scientific reviews are valid for the predicate tobacco product identified in this memo.

4.1. CHEMISTRY

Chemistry reviews were completed by Zhong Li, Ph.D. on December 10, 2012, August 1, 2013, and March 17, 2014.

The final chemistry review concludes that the new tobacco product does not raise different questions of public health with regard to product composition. Significant product composition issues identified during the scientific review of the SE Report include:

- Inadequate characterization of tobacco and non-tobacco ingredients
- Lack of harmful and potentially harmful constituents (HPHC) information.

In response to FDA's scientific A/I letter and Preliminary Finding letter, the applicant provided the appropriate characterization of tobacco and non-tobacco ingredients used in the new and predicate tobacco products. The same type of tobacco (b) (4) and same packaging materials are utilized for the new and predicate products. The applicant claims that all non-tobacco ingredients used in the products are food grade materials. The only changes made in the new tobacco product compared to the predicate tobacco product was a (b) (4) The applicant provided acceptable data comparing the quantities of HPHCs in the new and predicate tobacco products, (b) (4) Therefore, the final chemistry review concludes that the new tobacco product does not raise different questions of public health with regard to product composition.

4.2. ENGINEERING

Engineering reviews were completed by James Cheng on December 11, 2012, Komal Ahuja on August 1, 2013, and Tiffany Petty on March 19, 2014.

The final engineering review concludes that the new tobacco product does not raise different questions of public health with regard to product design. Significant product design issues identified during the scientific review of the SE Report include:

(b) (4)

The applicant did not provide (b) (4) for the new and predicate tobacco products. Instead, the applicant provided for the length, diameter, and weight of the bit. The dimensions of the new and predicate tobacco products are comparable. Therefore, the release of constituents from the new and predicate tobacco products is expected to be the same. Additionally, the applicant submitted (b) (4)

Therefore, the final engineering review concludes that the new tobacco product does not raise different questions of public health with regards to product design.

4.3. MICROBIOLOGY

A microbiology review was completed by Norma Duran on July 29, 2013.

The microbiology review concludes that the new tobacco product does not raise different questions of public health with regard to product microbiology. The significant product microbiology issue identified during the scientific review of the SE Report is product stability. The applicant provided stability data for the new and predicate tobacco products. (b) (4)

Therefore, the microbiology review concludes that the new tobacco product does not raise different questions of public health with regards to product microbiology.

4.4. TOXICOLOGY

Toxicology reviews were completed by Michael Orr, Ph.D., DABT on December 11, 2012, and October 11, 2013.

The final toxicology review concludes that the new tobacco product does not raise different questions of public health with regard to product toxicity. (b) (4) [redacted] Therefore, the toxicology review concludes that the new tobacco product does not raise different questions of public health.

4.5. SOCIAL SCIENCE

Social science reviews were completed by Amber Koblitz, Ph.D., M.P.H. on August 9, 2013, and April 4, 2014.

The final social science review concludes that the new tobacco product does not raise different questions of public health with regard to product appeal. The applicant provided a health information summary in compliance with section 910(a)(4) of the FD&C Act. The review concludes that the summary is acceptable. Overall, the social science review concludes that the differences in product appeal between the new and predicate tobacco products are such that the new tobacco product does not raise different questions of public health.

5. ENVIRONMENTAL DECISION

An environmental assessment was provided by the applicant. A finding of no significant impact (FONSI) was signed by Kimberly Benson Ph.D. on June 20, 2014. The FONSI was supported by an environmental assessment prepared by Ronald Edwards, M.S. dated June 20, 2014.

6. CONCLUSION AND RECOMMENDATION

The key differences in characteristics between the new and predicate tobacco products consist primarily of the following:

(b) (4) [redacted]

Removal of two chewing tobacco bit flavors: mint and citrus

The HPHC data indicates that these differences in characteristics do not cause the new tobacco product to be more toxic than the predicate tobacco products. More specifically, (b) (4) [redacted] were similar between the new and predicate tobacco products. Furthermore, the applicant provided stability data for the new and predicate tobacco products. (b) (4) [redacted]

The predicate tobacco product meets statutory requirements because it is a grandfathered product (i.e., was commercially marketed in the United States as of February 15, 2007).

The new tobacco product is currently in compliance with the FD&C Act. In addition, all of the scientific reviews conclude that the differences between the new and predicate tobacco products are such that the new tobacco product does not raise different questions of public health. I concur with these reviews and recommend that an SE order letter be issued.

In addition, an order letter can be issued because FDA examined the environmental effects of finding the new tobacco product substantially equivalent and made a finding of no significant impact.

An SE order letter should be issued for the new tobacco product in SE0004021, as identified on the cover page of this memo.