Technical Project Lead (TPL) Memorandum:

SE Reports SE0004017, SE0004018, SE0004019, SE0004020

SE0004017: Oliver Twist Original, Chewing Tobacco Bits	
Package Size	7 grams[1]
Package Type	Plastic can
SE0004018: Oliver Twist Tropical, Chewing Tobacco Bits	
Package Size	7 grams
Package Type	Plastic can
SE0004019: Oliver Twist Sunberry, Chewing Tobacco Bits	
Package Size	7 grams
Package Type	Plastic can
SE0004020: Oliver Twist Wintergreen, Chewing Tobacco Bits	
Package Size	7 grams
Package Type	Plastic can
Common Attributes of SE Reports	
Applicant	House of Oliver Twist A/S
Report Type	Regular
Product Category	Smokeless tobacco product
Product Sub-Category	Chewing Tobacco Bits
Recommendation	
Issue Substantial Equivalence (SE) orders	

[1] In an amendment of SE0004017, the applicant provides two package sizes for the new and predicate products. FDA's review of the SE Report only considers the original package size (7 grams).

Technical Project Lead (TPL):

Digitally signed by Matthew R. Holman -S
Date: 2014.05.08 22:55:39 -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: 2014.05.09 06:45:53 -04'00'

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

TABLE OF CONTENTS

1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCT

The applicant submitted the following predicate tobacco product:

Table 1. Predicate Tobacco Products

Oliver Twist Original (SE0004017)	
Product Name	Oliver Twist Original
Package Size	7 grams
Oliver Twist Tropical (SE0004018)	
Product Name	Oliver Twist Tropical
Package Size	7 grams
Oliver Twist Sunberry (SE0004019)	
Product Name	Oliver Twist Sunberry
Package Size	7 grams
Oliver Twist Wintergreen (SE0004020)	
Product Name	Oliver Twist Wintergreen
Package Size	7 grams

The predicate tobacco products are manufactured by House of Oliver Twist A/S. They are smokeless tobacco products, chewing tobacco bits.

1.2. REGULATORY ACTIVITY RELATED TO THIS MEMO

The applicant submitted the four original SE Reports listed in Table 2 of this memo. FDA sent the applicant administrative advice and information request letters (A/I letters) for these SE Reports. In response, the applicant submitted amendments to the original SE Reports (see Table 2). Following our review of the original and amended SE Reports, we sent a scientific A/I letter to the applicant in March 2013. The applicant responded to the scientific A/I letter by amending their SE Reports (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 their SE Reports (see Table 2).

Table 2. SE Reports and Amendments

Product Name	SE Report	Amendments
Oliver Twist Original	SE0004017	SE0004248 SE0008753 SE0010106 SE0010121 SE0010131 SE0010287 SE0010326
Oliver Twist Tropical	SE0004018	SE0004613 SE0007979 SE0008753 SE0010106 SE0010121 SE0010131 SE0010287 SE0010326
Oliver Twist Sunberry	SE0004019	SE0004613 SE0008753 SE0010106 SE0010121 SE0010131 SE0010287 SE0010326
Oliver Twist Wintergreen	SE0004020	SE0004550 SE0008753 SE0010106 SE0010121 SE0010131 SE0010287 SE0010326

1.3. SCOPE OF MEMO

This memo captures all administrative, compliance, and scientific reviews completed for SE0004017, SE0004018, SE0004019, and SE0004020.

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)

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 these SE Reports are administratively incomplete. However, a memorandum by Anne Radway on May 7, 2014, that concluded these SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews on January 4, 2013, to determine whether the applicant established that the predicate tobacco products are grandfathered products (i.e., were commercially marketed as of February 15, 2007). The OCE review concludes that the predicate tobacco products are eligible predicate tobacco products, as the applicant has established that the predicate tobacco products are grandfathered.

The Office of Compliance and Enforcement (OCE) also completed reviews to determine whether the new tobacco products are 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 reviews dated April 30, 2014, conclude that the new tobacco products are in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

Scientific reviews were completed by the Office of Science (OS) for the following disciplines:

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 products do not raise different questions of public health with regard to product composition. Significant product composition issues identified during the scientific review of the SE Reports 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 products. The same type of tobacco (b) (4) and same packaging materials are utilized for all new and corresponding 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 products compared to the corresponding predicate products was a (b) (4)

The applicant provided acceptable data comparing the quantities of HPHCs in the predicate and new products, (b) (4)

Therefore, the final chemistry review concludes that the new tobacco products do 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 products do not raise different questions of public health with regard to product design. Significant product design issues identified during the scientific review of the SE Reports include:

(b) (4)

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

Therefore, the final engineering review concludes that the new tobacco products do 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 products do 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 Reports is product stability. The applicant provided stability data for the new and predicate products. (b) (4)

(b) (4) Therefore, the microbiology review concludes that the new tobacco products do 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 products do not raise different questions of public health with regard to product toxicity. (b) (4) Therefore, the toxicology review concludes that the new tobacco products do 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 products do 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 predicate and corresponding new tobacco products are such that the new tobacco products do 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 RADM David L. Ashley on May 5, 2014. The FONSI was supported by an environmental assessment prepared by Ronald Edwards, M.S. dated May 2, 2014.

6. CONCLUSION AND RECOMMENDATION

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

(b) (4)

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

The predicate tobacco products meet statutory requirements because they are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007).

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

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

SE order letters should be issued for the new tobacco products in SE0004017, SE0004018, SE0004019, and SE0004020, as identified on the cover page of this memo.