U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

March 29, 2019

SUBSTANTIALLY EQUIVALENT

House of Oliver Twist A/S
Attention: Lisette Albrecht, Research and Quality
Borstenbindervej 1
5230 Odense M. Denmark

FDA Submission Tracking Numbers (STNs): MULTIPLE STNs, SEE APPENDIX A

Dear Ms. Albrecht:

The Food and Drug Administration (FDA) completed review of your Reports 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 tobacco products specified in Appendix A.

Based on our review of your SE Reports, we find the new tobacco products are substantially equivalent to the corresponding eligible predicate tobacco products, specified in Appendix A.

Under the provisions of section 910 and 905(j) of the FD&C Act, you may continue to legally market the new tobacco products specified in Appendix A.

To fulfill the provisions of section 910(a)(4) of the FD&C Act, you opted not to provide an adequate summary of any health information related to the new tobacco products with your application, but stated that such information will be available upon request by any person. Consistent with the requirements of Section 910(a)(4), you may wish to consider providing the following when information is requested:

A. A copy of your final SE Reports upon which our order was based, redacted only to the extent necessary to exclude patient identifiers, and trade secret and confidential commercial information as defined in 21 CFR § 20.61 and 20.63 and;
B. Any research or data you have in your possession or otherwise know of specifically regarding the adverse health effects of the new tobacco product or the following statement if such statement is accurate: "[Insert manufacturer name] does not have or know of any research or data regarding any adverse health effects specifically related to [insert tobacco product name]".

Alternatively, you may provide the following when information is requested:

A. Description of the new tobacco products;
B. Description of the predicate tobacco products;
C. List of all differences in characteristics between the predicate and new tobacco products;
D. Summary of the evidence and scientific rationale concerning why the differences in characteristics do not raise different questions of public health; and
E. Any research or data you have in your possession or otherwise know of regarding the adverse

health effects of the new tobacco product or the following statement if such statement is accurate: "[Insert manufacturer name] does not have or know of any research or data regarding any adverse health effects specifically related to [insert tobacco product name]".

There may be other accurate, complete, and not false or misleading ways to satisfy the requirements of Section 910(a)(4) not included above. If you wish to discuss other ways to meet the requirements of 910(a)(4), submit a meeting request to FDA.

In accordance with 40 CFR 1506.6, we will make publicly available the finding that these marketing authorizations are in a class of actions categorically excluded under 21 CFR 25.35(a). No extraordinary circumstances exist for this action.

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

The finding that your products are substantially equivalent to the predicate products is based upon the information you provided in your SE Reports and the standards contained in the FD&C Act, Section 910(a)(3). These marketing orders are 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 products specified in Appendix A, 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 that the tobacco products specified in Appendix A comply 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)[1] using eSubmitter (http://www.fda.gov/ForIndustry/FDAeSubmitter).

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

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 the FDA Electronic Submission Gateway (ESG) are generally available 24 hours a day, seven days a week; if the upload is successful, submissions are considered received by DCC on the day of upload. Submissions delivered to DCC by courier 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 or before the preceding business day. We are unable to accept regulatory submissions by e-mail.

If you have any questions, you may contact Emily R. Busta, MS, Regulatory Health Project Manager, at (240) 402-9078 or Emily.Busta@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2019.03.29 14:00:34 -04'00'

Matthew R. Holman, Ph.D.
Director
Office of Science
Center for Tobacco Products

Enclosure- Appendix A: List of New Tobacco Products Subject of This Letter

Appendix A

List of new tobacco products that FDA has determined are substantially equivalent when compared to its corresponding predicate tobacco product.

Common Attributes of SE Reports	
Date of Submission:	March 21, 2011
Date of Receipt:	March 23, 2011
Product Manufacturer:	House of Oliver Twist A/S
Product Category:	Smokeless Tobacco Products
Product Sub-Category:	Portioned Chewing Tobacco (SE0002651 and SE0015071 as part of a smokeless tobacco co-package)
New Tobacco Product Specific Attributes	
Submission Tracking Number	SE0002649
Product Name:[2] 2	Oliver Twist Original, Chewing Tobacco Bits[3]
Package Type:	Plastic container with an aluminum/plastic pouch
Package Quantity:	7.0 g
Characterizing Flavor:	None[4]
Portion Mass:[5]	200 mg/bit
Portion Length:	9.5 mm
Portion Width:[6]	4.6 mm
Portion Thickness:[6]	4.6 mm
Predicate Tobacco Product Specific Attributes	
Product Name:[2]	Oliver Twist Original[3]
Package Type:	Plastic container with an aluminum/plastic pouch
Package Quantity:	7.0 g
Characterizing Flavor:	None[4]
Eligibility Status:	Grandfathered
Portion Mass:[5]	200 mg/bit
Portion Length:	9.5 mm
Portion Width:[6]	4.6 mm
Portion Thickness:[6]	4.6 mm

[2] Brand/sub-brand or other commercial name used in commercial distribution.

[3] Per amendments SE0015090 and SE0015106, tobacco bits are manufactured by (b) (4) and then (b) (4). Due to the natural variation in tobacco leaf size, the (b) (4) aspect of manufacture, and other typical aspects of manufacturing variation; tobacco bits vary in mass. Therefore, in this instance, the portion count is not needed because portion count is dictated by package quantity. For example, in SE0002649, the new and predicate products contain 7 g of product, regardless of the number of bits.

[4] The Oliver Twist Original variety does not have a characterizing flavor, noted with "none" in the description of SE0002649 per the May 14, 2018 Compliance Review Addendum.

[5] Providing portion mass plus two of the three portion dimensions (along with other specified properties) will allow for full identification of portioned moist snuff, snus, and chewing tobacco products.

[6] Bits are cylindrical, width and thickness represent diameter.

New Tobacco Product Specific Attributes	
Submission Tracking Number	SE0002651:
Product Name:[2]	Oliver Twist Original, Chewing Tobacco Bits[3]
Package Type:	Aluminum/plastic pouch
Package Quantity:	0.5 g[7]
Characterizing Flavor:	None[4]
Portion Mass:[5]	200 mg/bit
Portion Length:	9.5 mm
Portion Width:[6]	4.6 mm
Portion Thickness:[6]	4.6 mm
Predicate Tobacco Product Specific Attributes	
Product Name:[2]	Oliver Twist Multipack[3]
Package Type:	Plastic container with 6 aluminum/plastic pouches
Package Quantity:	3.0 g
Characterizing Flavor:	Original[4], Sunberry, Wintergreen, Tropical, Citrus, Mint
Eligibility Status:	Grandfathered
Portion Mass:[5]	200-250 mg/bit[8]
Portion Length:	9.5 mm
Portion Width:[6]	4.6-5.0 mm[8]
Portion Thickness:[6]	4.6-5.0 mm[8]
Additional Property:	Variety pack of 6 flavors

[7] The package quantity was calculated by FDA based on the average number of bits per pouch and the average mass of a single bit submitted by the applicant. For example, per amendment SE0015106, in SE0015071 90% of the products contain between 2 and 3 bits and the average mass of a bit is 240 mg {[(2 bits*240 mg) + (3 bits*240 mg)]/2} = 600 mg (0.6 g.)

[8] May vary by flavor

New Tobacco Product Specific Attributes	
Submission Tracking Number	SE0015071
Product Name:[2]	Oliver Twist Sunberry, Chewing Tobacco Bits[3]
Package Type:	Aluminum/plastic pouch
Package Quantity:	0.6 g[7]
Characterizing Flavor:	Sunberry
Portion Mass:[5]	240 mg/bit
Portion Length:	9.5 mm
Portion Width:[6]	5.0 mm
Portion Thickness:[6]	5.0 mm
Predicate Tobacco Product Specific Attributes	
Product Name:[2]	Oliver Twist Multipack[3]
Package Type:	Plastic container with 6 aluminum/plastic pouches
Package Quantity:	3.0 g
Characterizing Flavor:	Original[4], Sunberry, Wintergreen, Tropical, Citrus, Mint
Eligibility Status:	Grandfathered
Portion Mass:[5]	200-250 mg/bit[8]
Portion Length:	9.5 mm
Portion Width:[6]	4.6-5.0 mm[8]
Portion Thickness:[6]	4.6-5.0 mm[8]
Additional Property:	Variety pack of 6 flavors