

Technical Project Lead (TPL) Review of SE Reports

New Products Subject of this Review	
Submission tracking numbers (STNs)	Multiple STNs, see Appendix A
Common Attributes	
Submission date	August 27, 2020
Receipt date	September 4, 2020
Applicant	Inter-Continental Trading USA, Inc.
Product manufacturer	Inter-Continental Trading USA, Inc.
Application type	Same Characteristics
Product category	see Appendix A
Product subcategory	see Appendix A
Cross-Referenced Submissions	
All new products	None
Supporting FDA Memoranda Relied Upon in this Review	
All new products	Product Quantity Changes in Substantial Equivalence Reports (SE Reports) for Statutorily Regulated Tobacco Products (December 7, 2017)
Recommendation	
Issue Substantially Equivalent (SE) orders for the new tobacco products subject of this review.	

Technical Project Lead (TPL):

For Digitally signed by Avena Russell -S
Date: 2021.08.10 17:20:25 -04'00'

Habibah Jackson
Branch Chief, Division of Regulatory Project Management
Office of Science

Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Digitally signed by Matthew R. Holman -S
Date: 2021.08.11 11:45:52 -04'00'

Matthew R. Holman, Ph.D.
Director
Office of Science

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1. BACKGROUND

1.1. NEW AND PREDICATE PRODUCTS

The applicant submitted information for the new and predicate products listed in detail in the Appendix.

1.2. REGULATORY ACTIVITY

On September 4, 2020, FDA received 25 Product Quantity Change SE Reports from Inter-Continental Trading USA, Inc. On November 17, 2020, FDA issued Acceptance letters to the applicant. FDA's Office of Compliance and Enforcement (OCE) contacted the applicant on May 27, 2021, to request additional information to complete predicate eligibility review. FDA received the applicant's response to OCE's request on June 2, 2021, (SE0024640). Additionally, FDA's Division of Regulatory Project Management (DRPM) contacted the applicant on June 29, 2021, to request additional information to address certain discipline reviewer concerns specific to SE0021946, SE0021951, SE0021953, and SE0021968. FDA received the applicant's response to DRPM's request on July 02, 2021 (SE0024738).

See Appendices for products and amendments.

1.3. SCOPE OF REVIEW

This review captures all compliance, regulatory, and scientific reviews completed for the new products that are the subject of this review.

Table 1. Disciplines reviewed

Discipline	Cycle 1	
	Reviewer	Review Date
Regulatory	Fiona Kiprop	8/4/2021
Environmental Science	Christy Leppanen	6/30/2021

2. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the predicate products are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007). The OCE reviews dated June 22, 2021, conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate products are grandfathered and, therefore, are eligible predicate products.

OCE also completed a review to determine whether the new products are in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) (see section 910(a)(2)(A)(i)(II) of the FD&C Act). The OCE review dated July 21, 2021, concludes that the new products are in compliance with the FD&C Act.

3. SCIENTIFIC REVIEW

Full scientific review was not initiated by the Office of Science (OS) because the product characteristics of the new and corresponding predicate tobacco products are identical except for the following change in product quantity and container closure system:

Change in Product Quantity

SE Report	New Product	Predicate Product	% Change
SE0021828, SE0021957, SE0021966, SE0021967, SE0021973	5 lb	16 oz	↑400
SE0021945, SE0021946, SE0021955, SE0021959, SE0021961, SE0021965	6 oz	16 oz	↓63
SE0021948, SE0021950, SE0021952	1 oz	6 oz	↓83
SE0021956, SE0021964	8 oz	16 oz	↓50
SE0021962	1 oz	16 oz	↓94
SE0021970	5 lb	6 oz	↑1233
SE0021974	6 oz	13 oz	↓54
SE0021975, SE0021979	8 oz	13 oz	↓38
SE0021980	16 oz	13 oz	↑23

Change in Container Closure

SE Report	New Product	Predicate Product
SE0021828, SE0021945-SE0021946, SE0021955-SE0021957, SE0021959, SE0021961-SE0021962, SE0021964-SE0021967, SE0021973	Foil Bag	Plastic Bag
SE0021948, SE0021950-SE0021953, SE0021968, SE0021970, SE0021974-SE0021975, SE0021979-SE0021980	Foil Bag	Foil-line Paperboard Cannister

OS prepared memoranda¹ summarizing its current thinking on product quantity changes. Existing data on product quantity changes are limited and do not address the size threshold (i.e., how much of a change in product quantity) necessary to raise different questions of public health. With respect to product quantity decreases, even though some of the currently available scientific evidence is specific to tobacco products, the studies do not separate out the effect of reduced price from size on consumption or initiation. Thus, based upon the currently available science and CTP's experience in reviewing SE Reports, product quantity changes do not cause new tobacco products to raise different questions of public health. Therefore, scientific review is unnecessary.

Additionally, differences in container closure systems could potentially affect moisture content which in turn may impact microbial growth and carcinogenic tobacco specific nitrosamine (TSNA)

¹ See memorandum on product quantity changes, dated December 7, 2017, and addendum for deemed tobacco products, dated December 30, 2019.

formation over shelf life of the new products.² The applicant did not provide any moisture content data for the new or corresponding predicate products to support this change; however, the predicate products are roll-your-own tobacco products, which are considered non-moist. The applicant provided a certification statement that the new and corresponding predicate products differ in only product quantity and/or container closure systems and there are no changes in *per weight* composition, other design features, heating source, or other features. As the predicate products are non-moist and the applicant certifies the per weight composition is identical between the new and corresponding predicate products, the lack of moisture content data would not raise concerns from a microbiology perspective. Consequently, in this particular case of non-moist products, the change in container closure systems between the new and corresponding predicate products does not cause the new products to raise different questions of public health.

4. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Luis Valerio, Ph.D., ATS on June 30, 2021. The FONSI was supported by an environmental assessment prepared by FDA on June 30, 2021.

5. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and corresponding predicate tobacco products are identical except for the following change in product quantity and container closure system:

- 400% increase (1 lb [16 oz] to 5 lb) - SE0021828, SE0021957, SE0021966, SE0021967, SE0021973
- 63% decrease (16 oz to 6 oz) - SE0021945, SE0021946, SE0021955, SE0021959, SE0021961, SE0021965
- 83% decrease (6 oz to 1 oz) - SE0021948, SE0021950, SE0021952
- 50% decrease (16 oz to 8 oz) - SE0021956, SE0021964
- 94% decrease (16 oz to 1 oz) – SE0021962
- 1233% increase (6 oz to 5lb) – SE0021970
- 54% decrease (13 oz to 6 oz) – SE0021974
- 38% decrease (13 oz to 8 oz) – SE0021975, SE0021979
- 23% increase (13 oz to 16 oz) – SE0021980
- Plastic Bag to Foil Bag – SE0021828, SE0021945-SE0021946, SE0021955-SE0021957, SE0021959, SE0021961-SE0021962, SE0021964-SE0021967, SE0021973
- Foil-line Paperboard Cannister to Foil Bag- SE0021948, SE0021950 – SE0021953, SE0021968, SE0021970, SE0021974-SE0021975, SE0021979-SE0021980

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

The new products are currently in compliance with the FD&C Act. I concur with these reviews and recommend that SE order letters be issued.

² Djordjevic MV, Brunnemann KD, Hoffmann D. The need for regulation of carcinogenic N-nitrosamines in oral snuff. Food Chem Toxicol. 1993;31(7):497-501

FDA examined the environmental effects of finding these new products substantially equivalent and made a finding of no significant impact.

6. APPENDICES

Appendix A. New and predicate products

Common Attributes of SE Reports		
Submission date	August 27, 2020	
Receipt date	September 04, 2020	
Product manufacturer	Inter-Continental Trading USA, Inc.	
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0021828	GF2116181
Product name	OHM Bold 5lb	Smoker's Gold 1LB Regular
Product category	Pipe Tobacco Products	Roll-your-own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-your-own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Foil bag	Plastic bag
Package quantity	5 lb ³	16 oz
Characterizing flavor	None	None
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0021945	GF2116187
Product name	752 Green 6oz	Smoker's Gold 1LB Menthol
Product category	Pipe Tobacco Products	Roll-your-own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-your-own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Foil bag	Plastic Bag
Package quantity	6 oz	16 oz
Characterizing flavor	Menthol	Menthol
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0021946	GF2116181
Product name	752 Red 6oz	Smoker's Gold 1LB Regular
Product category	Pipe Tobacco Products	Roll-your-own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-your-own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Foil bag	Plastic bag
Package quantity	6 oz	16 oz
Characterizing flavor	None	None
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0021948	GF2116177
Product name	OHM Au Naturelle Gold 1oz	Cutlass Ultra Light 6oz Can
Product category	Pipe Tobacco Products	Roll-your-own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-your-own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Foil bag	Foil-line paperboard cannister
Package quantity	1 oz	6 oz
Characterizing flavor	None	None

³ 5 lb is equal to 80 oz

Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0021950	GF2116179
Product name	OHM Au Naturalle Menthol 1oz	Cutlass Menthol Light 6oz Can
Product category	Pipe Tobacco Products	Roll-your-own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-your-own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Foil bag	Foil-line paperboard cannister
Package quantity	1 oz	6 oz
Characterizing flavor	Menthol	Menthol
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0021951	GF2116179
Product name	OHM Au Naturall'e Menthol 6oz	Cutlass Menthol Light 6oz Can
Product category	Pipe Tobacco Products	Roll-your-own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-your-own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Foil bag	Foil-line paperboard cannister
Package quantity	6 oz	6 oz
Characterizing flavor	Menthol	Menthol
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0021952	GF2116177
Product name	OHM Au Naturalle Red 1oz	Cutlass Ultra Light 6oz Can
Product category	Pipe Tobacco Products	Roll-your-own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-your-own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Foil bag	Foil-line paperboard cannister
Package quantity	1 oz	6 oz
Characterizing flavor	None	None
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0021953	GF2116177
Product name	OHM Au Naturall'e Red 6oz	Cutlass Ultra Light 6oz Can
Product category	Pipe Tobacco Products	Roll-your-own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-your-own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Foil bag	Foil-line paperboard cannister
Package quantity	6 oz	6 oz
Characterizing flavor	None	None
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0021955	GF2116183
Product name	OHM Blue 6oz	Smoker's Gold 1LB Light
Product category	Pipe Tobacco Products	Roll-your-own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-your-own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Foil bag	Plastic bag
Package quantity	6 oz	16 oz
Characterizing flavor	None	None

Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0021956	GF2116183
Product name	OHM Blue 8oz	Smoker's Gold 1LB Light
Product category	Pipe Tobacco Products	Roll-your-own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-your-own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Foil bag	Plastic bag
Package quantity	8 oz	16 oz
Characterizing flavor	None	None
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0021957	GF2116183
Product name	OHM Blue 5lb	Smoker's Gold 1LB Light
Product category	Pipe Tobacco Products	Roll-your-own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-your-own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Foil bag	Plastic bag
Package quantity	5 lb ³	16 oz
Characterizing flavor	None	None
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0021959	GF2116181
Product name	OHM Bold 6oz	Smoker's Gold 1LB Regular
Product category	Pipe Tobacco Products	Roll-your-own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-your-own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Foil bag	Plastic bag
Package quantity	6 oz	16 oz
Characterizing flavor	None	None
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0021961	GF2116183
Product name	752 Gold 6oz	Smoker's Gold 1LB Light
Product category	Pipe Tobacco Products	Roll-your-own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-your-own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Foil bag	Plastic bag
Package quantity	6 oz	16 oz
Characterizing flavor	None	None
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0021962	GF2116187
Product name	OHM Menthol 1oz	Smoker's Gold 1LB Menthol
Product category	Pipe Tobacco Products	Roll-your-own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-your-own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Foil bag	Plastic Bag
Package quantity	1 oz	16 oz
Characterizing flavor	Menthol	Menthol

Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0021964	GF2116187
Product name	OHM Menthol 8oz	Smoker's Gold 1LB Menthol
Product category	Pipe Tobacco Products	Roll-your-own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-your-own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Foil bag	Plastic Bag
Package quantity	8 oz	16 oz
Characterizing flavor	Menthol	Menthol
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0021965	GF2116189
Product name	OHM Menthol Gold 6oz	Smoker's Gold 1LB Menthol Light
Product category	Pipe Tobacco Products	Roll-your-own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-your-own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Foil bag	Plastic Bag
Package quantity	6 oz	16 oz
Characterizing flavor	Menthol	Menthol
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0021966	GF2116189
Product name	OHM Menthol Gold 5lb	Smoker's Gold 1LB Menthol Light
Product category	Pipe Tobacco Products	Roll-your-own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-your-own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Foil bag	Plastic Bag
Package quantity	5 lb ³	16 oz
Characterizing flavor	Menthol	Menthol
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0021967	GF2116187
Product name	OHM Menthol 5lb	Smoker's Gold 1LB Menthol
Product category	Pipe Tobacco Products	Roll-your-own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-your-own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Foil bag	Plastic Bag
Package quantity	5 lb ³	16 oz
Characterizing flavor	Menthol	Menthol
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0021968	GF2116177
Product name	OHM Natural 6oz	Cutlass Ultra Light 6oz Can
Product category	Pipe Tobacco Products	Roll-your-own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-your-own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Foil bag	Foil-line paperboard cannister
Package quantity	6 oz	6 oz
Characterizing flavor	None	None

Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0021970	GF2116177
Product name	OHM Natural 5lb	Cutlass Ultra Light 6oz Can
Product category	Pipe Tobacco Products	Roll-your-own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-your-own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Foil bag	Foil-line paperboard cannister
Package quantity	5 lb ³	6 oz
Characterizing flavor	None	None
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0021973	GF2116183
Product name	OHM Silver 5lb	Smoker's Gold 1LB Light
Product category	Pipe Tobacco Products	Roll-your-own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-your-own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Foil bag	Plastic bag
Package quantity	5 lb ³	16 oz
Characterizing flavor	None	None
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0021974	GF2116174
Product name	OHM Turkish Red 6oz	Cutlass Regular 13oz Can
Product category	Pipe Tobacco Products	Roll-your-own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-your-own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Foil bag	Foil-line paperboard cannister
Package quantity	6 oz	13 oz
Characterizing flavor	None	None
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0021975	GF2116174
Product name	OHM Turkish Red 8oz	Cutlass Regular 13oz Can
Product category	Pipe Tobacco Products	Roll-your-own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-your-own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Foil bag	Foil-line paperboard cannister
Package quantity	8 oz	13 oz
Characterizing flavor	None	None
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0021979	GF2116176
Product name	OHM Turkish Yellow 8oz	Cutlass Light 13oz Can
Product category	Pipe Tobacco Products	Roll-your-own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-your-own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Foil bag	Foil-line paperboard cannister
Package quantity	8 oz	13 oz
Characterizing flavor	None	None

Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0021980	GF2116176
Product name	OHM Turkish Yellow 16oz	Cutlass Light 13oz Can
Product category	Pipe Tobacco Products	Roll-your-own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-your-own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Foil bag	Foil-line paperboard cannister
Package quantity	16 oz	13 oz
Characterizing flavor	None	None

Appendix B. Amendments

Submission Date	Receipt Date	Amendment	Applications being amended	Reviewed	Brief Description
May 27, 2021	June 2, 2021	SE0024640	All	Yes	Correction or clarification to original submission
June 29, 2021	July 2, 2021	SE0024738	SE0021946, SE0021951, SE0021953, SE0021968	Yes	Correction or clarification to original submission.