



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

August 11, 2021

SUBSTANTIALLY EQUIVALENT

Inter-Continental Trading USA, Inc.
Attention: Thomas Burns, Project Lead
1601 West Algonquin Road
Mount Prospect, IL 60056

FDA Submission Tracking Numbers (STNs): Multiple STNs, see Appendix A

Dear Mr. Burns:

We completed our review of your SE Reports¹ and determined that the new tobacco products are substantially equivalent to the corresponding predicate tobacco products listed in Appendix A and are in compliance with the requirements of the FD&C Act. 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 products subject of this letter.

Our finding does not mean we “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).

For information on how to fulfill the provisions of section 910(a)(4) of the FD&C Act, refer to Appendix B.

In accordance with 40 CFR 1506.6, we will make your Environmental Assessment (EA) publicly available.

All regulated tobacco products, including the tobacco products specified in Appendix A, are subject to the requirements of the FD&C Act and its implementing regulations. It is your responsibility to ensure the tobacco products specified in Appendix A complies with all applicable statutory and regulatory requirements. FDA will monitor your compliance with all applicable statutes and regulations.

¹ Substantially Equivalent (SE) Reports submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

If you have any questions, please contact Crystal Ceasar, Regulatory Health Project Manager, at (240) 420-4793 or Crystal.Ceasar@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2021.08.11 11:46:40 -04'00'

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

Enclosures:

Appendix A – New and Corresponding Predicate Tobacco Products Subject of This Letter
Appendix B – Health Information Summary

Appendix A²
New and Corresponding Predicate Tobacco Products Subject of This Letter

| 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 Naturalle 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 |

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

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

Health Information Summary

Your SE Reports did not provide a summary of any health information related to the new tobacco products, required by section 910(a)(4) of the FD&C Act; however, your SE Reports stated that such information will be available upon request to 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 the Substantially Equivalent 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.
- B. Any research or data you have in your possession or otherwise know of specifically regarding the adverse health effects of the new tobacco products, 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:

- Description of the new tobacco products
- Description of the predicate tobacco products
- List of all differences in characteristics between the new and predicate tobacco products
- Summary of the evidence and scientific rationale concerning why the differences in characteristics do not raise different questions of public health
- 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 section 910(a)(4), submit a meeting request to us.