FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review of SE Reports

New Products Subject of this Review[1]	
STNs	SE0016733.PD1, SE0016734.PD1, SE0016735.PD2, SE0016736.PD2, SE0017458.PD1, SE0017587.PD1
Common Attributes	
Submission date	June 22, 2020; August 24, 2020
Receipt date	June 22, 2020; August 24, 2020
Applicant	BBK Tobacco & Foods LLP dba HBI International
Product manufacturer	BBK Tobacco & Foods LLP dba HBI International
Application type	Regular
Product category	Roll-Your-Own Tobacco Products
Product subcategory	Rolling Paper; Paper Tip
Cross-Referenced Submissions	
SE0016733.PD1	(b)(4)
Supporting FDA Memoranda Relied Upon in this Review	
All SE Reports	• Memorandum, Equivalence Testing for SE Evaluation (February 24, 2017). • Addendum to February 24, 2017, Equivalence Testing for SE Evaluations Memo (April 16, 2019). • Addendum to Memorandum: Product quantity changes in Substantial Equivalence Reports (SE Reports) for statutorily regulated tobacco products (December 31, 2019).
Recommendation	
Issue Substantially Equivalent (SE) orders for the new products subject of this review.	

Technical Project Lead (TPL):

Digitally signed by Karen M. Coyne -S
Date: 2022.09.28 17:01:18 -04'00'

Karen Coyne, Ph.D.
Associate Director, Division of Product Science
Office of Science

Signatory Decision: Concur with TPL recommendation and basis of recommendation

Todd L. Cecil -S Digitally signed by Todd L. Cecil -S
Date: 2022.09.29 14:30:33 -04'00'

Todd L. Cecil, Ph.D.
Acting Director
Office of Science

[1] Product details, amendments, and dates provided in the Appendix. SE means substantial equivalence (report). STN means submission tracking number.

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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

See Appendix for products and amendments.

1.3. SCOPE OF REVIEW

This review captures all compliance, regulatory, and scientific reviews completed for the new products subject of this review. For SE0016733.PD1, tobacco product master file (TPMF), (b)(4) was reviewed by chemistry on March 22, 2021.

Table 1. Disciplines reviewed

STNs	Discipline	Cycle 1	
		Reviewer(s)	Review Date
SE0016733.PD1	Regulatory	Carlos Suarez	7/7/2020
SE0016734.PD1	Regulatory	Jessica Scudder	6/26/2020
SE0016735.PD2 and SE0016736.PD2	Regulatory	Kristopher G. Van Amburg	6/29/2020
SE0017458.PD1 and SE0017587.PD1	Regulatory	Kim C. Jordan	9/14/2020
All STNs	Chemistry	DeLauren McCauley	6/16/2021
All STNs	Engineering	Mary Searing	7/7/2021
All STNs	Toxicology	Atinuke Ajiboye	7/10/2021
All STNs	Environmental Science	Vyomesh Patel	4/20/2021

2. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the predicate products in SE0016733.PD1, SE0016734.PD1, SE0016735.PD2, and SE0016736.PD2 are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007). The OCE reviews dated June 1, 2021 (SE0016733.PD1-SE0016735.PD2) and June 7, 2021 (SE0016736.PD2), conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate products are grandfathered and, therefore, are eligible predicate products.

The predicate product in SE0017458.PD1 and SE0017587.PD1 was determined to be substantially equivalent by FDA under SE0015554. Therefore, the predicate product is an eligible predicate product.

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 reviews dated June 1, 2021, and June 13, 2022, conclude that the new products are in compliance with the FD&C Act.

3. SCIENTIFIC REVIEW

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

3.1. CHEMISTRY

The final chemistry review concludes that the new products have different characteristics compared to the corresponding predicate products, but the differences do not cause the new products to raise different questions of public health from a chemistry perspective.

The applicant submitted SE Reports for RYO rolling paper (SE0016733.PD1), rectangular paper tips (S0016734.PD1, SE0016735.PD2, and SE0016736.PD2), and cone tips (SE0017458.PD1 and SE0017587.PD1) and provided ingredient information and materials for the packaging and container closure system (CCS) for all SE Reports. Mainstream smoke (MSS) data was only provided for the new and predicate products in SE0016733.PD1.

For SE0016733.PD1, there are identical quantities of (b)(4) and (b)(4) in the new and predicate products. However, there is a quantity difference in (b)(4) an adhesive. The difference in adhesive is minor relative to the total quantity of ingredients in the new and predicate products and therefore the quantity difference in (b)(4) does not cause the new products to raise different questions of public health, from a chemistry perspective. The new product in SE0016733.PD1 has a physical "RAW" watermark, while the predicate product has a physical "HBI" watermark. Because the watermarks were applied with pressure, no additional ingredients were added to the paper. However, there is a 37% decrease in watermarked paper air permeability that may impact MSS yields. The watermarked paper air permeability differences are discussed below with the MSS data.

In SE0016734.PD1, SE0016735.PD2, SE0016736.PD2, SE0017458.PD1, and SE0017587.PD1, the ingredient quantity descriptors for the paper tips are expressed as "no more than" and "at least". The percentage differences between the new and corresponding predicate products are minimal and the products are not intended to be combusted during use. Additionally, in SE0017458.PD1 and SE0017587.PD1, the new products have a red "RAW" logo printed on them while the predicate products have a blue "ELEMENTS" logo. The applicant specified that the pre-rolled tips in SE0017458.PD1 and SE0017587.PD1 are intended to act as a holder for the rolling paper that is wrapped around the tips and thus the tips do not make direct contact with the user's mouth. Therefore, the paper tip ingredient quantities in the new and corresponding predicate products and the difference in printed logos in SE0017458.PD1 and SE0017587.PD1 do not to cause the new products to raise different questions of public health, from a chemistry perspective.

The CCS in SE0016733.PD1 is a cardboard box in the new product and a polystyrene box in the predicate. The difference in CCS in SE0016733.PD1 does not cause the new products to raise different questions of public health from a chemistry perspective. The CCS is identical in the new and corresponding predicate products in SE0016734.PD1, SE0016735.PD2, SE0016736.PD2, SE0017458.PD1, and SE0017587.PD1 and the new and grandfathered (GF) products in SE0017458.PD1 and SE0017587.PD1 and does not cause the new products to raise different questions of public health, from a chemistry perspective. There are package quantity changes in the new and corresponding predicate products in SE0016733.PD1 (shorter roll of paper) and SE0017587.PD1 (increased number of tips). Based on the currently available scientific evidence

regarding consumer perception and use, FDA has concluded that, at this time, a change in product quantity does not cause the new products to raise different questions of public health.

For MSS analysis in SE0016733.PD1, the applicant used a third-party lab, who authorized the applicant to reference their TPMF (b)(4) The TPMF contained sufficient information to support this review.

For SE0016733.PD1, the applicant provided details of harmful and potentially harmful constituent (HPHC) testing. American Spirit RYO tobacco was used to generate mainstream smoke yields for the new and predicate products under the Canadian Intense (CI) smoking regimen. The applicant provided tar, nicotine, and CO (TNCO) yields and HPHC data for total particulate matter (TPM), 1,3 butadiene, acetaldehyde, acetone, acrolein, acrylonitrile, (b)(4) benzo[a]pyrene (B[a]P), benzanthracene, benzene, benzofuran, (b)(4) catechol, chrysene, cresol (m+p), cresol (o), crotonaldehyde, ethylbenzene, (b)(4) (b)(4) formaldehyde, furan, (b)(4) isoprene, methyl-ethyl ketone, naphthalene, nitromethane, (b)(4) phenol, propionaldehyde, (b)(4) styrene, and toluene as well as puff counts for the new and predicate products. The TNCO and HPHC data were evaluated using a two one-sided t-test (TOST) equivalence test for mean smoke yields in the new and predicate products. All MSS yields in the new and predicate products were analytically equivalent and therefore do not cause the new products in SE0016733.PD1 to raise different questions of public health, from a chemistry perspective.

In SE0016733.PD1, there is a 40% decrease in paper length. The rolling paper is cut into sheets prior to forming the RYO cigarettes. A (b)(4) mm roll will produce fewer cigarettes than a (b)(4) mm roll, and, based on the evidence available at this time, a change in tobacco product quantity does not cause the new products to raise different questions of public health. Furthermore, because the MSS yields in the new and predicate products were analytically equivalent, the 37% increase in watermarked paper air permeability does not cause the new products to raise different questions of public health, from a chemistry perspective.

The applicant did not provide MSS yields using the paper tips in SE0016734.PD1. The chemistry review does not discuss the lack of smoke yield data. However, the length and width of the tips in the new and predicate products are identical. Since the tip dimensions are identical, if the same size rolling paper is used, there is expected to be no difference in the amount of tobacco used in the hand-rolled cigarette. Additionally, the minimal differences in ingredient quantities are not a concern because the tips are not burned and thus do not contribute to HPHC yields. Accordingly, the lack of MSS yields for the new and predicate products in SE0016734.PD1 does not cause the new product to raise different questions of public health from a chemistry perspective.

The applicant did not provide MSS yields using the paper tips in SE0016735.PD2 and SE0016736.PD2 to create test cigarettes to generate MSS data. MSS yields may be impacted by differences in design parameters, including decreased paper tip length (34%) and increased paper tip width (7%). The increased paper tip width will result in a shorter tobacco rod in the new compared to the predicate product when the paper tips are assembled using the same size RYO rolling paper. While there is variability in how a paper tip is rolled, the decreased paper tip length would likely result in a tip with a decreased diameter. A decrease in the tobacco rod length and a decrease is the diameter of the tobacco rod are expected to decrease the amount

of tobacco used, which is expected to lower mainstream smoke yields. Therefore, the differences in paper tip length and width in the new products in SE0016735.PD2 and SE0016736.PD2 do not cause new products to raise different questions of public health, from a chemistry perspective.

Additionally, for SE0017458.PD1 and SE0017587.PD1, the applicant did not provide MSS yields for the new, predicate, and GF products using the cone tips (new products) or cylindrical tips (predicate and GF products) since the products do not contain tobacco and are not combusted during smoking. While the new products are pre-rolled cones and (b)(4) when unrolled and the predicate and GF products are pre-rolled cylinders and rectangular rolling paper tips when unrolled, the area of the new and predicate unrolled paper tips and the new and GF unrolled paper tips are similar. Additionally, the new products are 17% longer, which would result in a shorter tobacco rod in the new product when the paper tips are assembled using the same size RYO rolling paper. Due to the variability in the way the cigarettes may be rolled using the tips, the similar paper area, and the increased length of the pre-rolled new products, the lack of MSS for the new, predicate, and GF products does not cause the new products to raise different questions of public health from a chemistry perspective.

Therefore, the differences in characteristics between the new and corresponding predicate products do not cause the new products to raise different questions of public health from a chemistry perspective.

3.2. ENGINEERING

The final engineering review concludes that the new products have different characteristics compared to the corresponding predicate products, but the differences do not cause the new products to raise different questions of public health from an engineering perspective.

For SE0016733.PD1, the applicant provided target specifications and range limits for length, width, base paper basis weight, and watermarked paper air permeability to characterize the new and predicate products. While paper mass wasn't provided, the new and predicate products are both rolls of paper rather than individual sheets, so base paper basis weight is more applicable in this case. There was a 37% increase in watermarked paper air permeability and a 40% decrease in paper length. Differences in watermarked paper air permeability and rolling paper length may impact smoke constituent yields, so these differences were deferred to chemistry.

For SE0016734.PD1, SE0016735.PD2, and SE0016736.PD2, the applicant provided tip length and width target specifications and range limits to characterize the new and predicate products. For SE0016734.PD1, the new and predicate products have identical tip length and tip width. Identical tip length and width do not cause the new product in SE0016734.PD1 to raise different questions of public health. For SE0016735.PD2 and SE0016736.PD2, the paper tip length of the new products decreases by 34% and the paper tip width increases by 7%. If the same size RYO paper is used, a difference in the paper tip length and/or width may result in a different tobacco mass used in the RYO cigarette due to possible differences in paper tip volume. Differences in tobacco mass may impact the amount of smoke constituents delivered to the user. For

SE0016735.PD2 and SE0016736.PD2, the differences in tip length and tip width were deferred to chemistry for the evaluation of TNCO.

For SE0017458.PD1 and SE0017587.PD1, the applicant provided target specifications and range limits to characterize the new and predicate products. For both SE Reports, the predicate product is a previously found substantially equivalent product, SE0015554. For the pre-rolled paper tips in SE0017458.PD1 and SE0017587.PD1, the new products are a cone while the predicate and grandfathered products (in SE0015554) are cylindrical. The new products are 17% longer, which would result in a shorter tobacco rod in the new product when the paper tips are assembled using the same size RYO rolling paper. The chemistry review evaluated the difference in length. Additionally, the area of the new products increases 4% compared to the predicate product and 6% compared to the grandfathered product. Considering the variability in the way cigarettes may be rolled using the tips, the differences in area are anticipated to be too small to impact the amount of tobacco mass used in the resulting rolled cigarette, and thus the smoke constituent yields.

Therefore, the differences in characteristics between the new and corresponding predicate products do not cause the new products to raise different questions of public health from an engineering perspective.

3.3. TOXICOLOGY

The final toxicology review concludes that the new products have different characteristics compared to the corresponding predicate products, but the differences do not cause the new products to raise different questions of public health from a toxicology perspective.

For SE0016733.PD1, the quantity of (b)(4) in the new product is 40% lower in the new product. Lower mass of the same ingredient in the new and predicate products does not cause the new products to raise new questions of public health, from a toxicological perspective. For the rolling paper tips in SE0016734.PD1, SE0016735.PD2, SE0016736.PD2, SE0017458.PD1, and SE0017587.PD1, the applicant provides the ingredients and estimated quantities or ranges for the new and corresponding predicate products. The applicant specifies that the tips are intended to act as a holder for RYO rolling papers or pre-rolled cones and that the papers are wrapped around the tip so that the tip does not make direct contact with the user's mouth. Furthermore, the ingredients in the tip are expected to be contained in the original non-combusted portion of the cigarette, and their release from the tip should be minimal or none; thus, exposure to these ingredients via the inhalation, oral, and dermal routes during normal cigarette consumption is expected to be minimal. In addition, these ingredients are not expected to be burned, volatilized, or to be a potential source of thermal degradation or pyrolysis to generate HPHCs for inhalation exposures. Therefore, the ingredients in the tips in the new products are unlikely to be a toxicological concern and do not cause the new products in SE0016734.PD1, SE0016735.PD2, SE0016736.PD2, SE0017458.PD1, and SE0017587.PD1 to raise different questions of public health from a toxicological perspective.

The measured air permeability of the watermarked paper is higher in the new product in SE0016733.PD1 compared to the predicate product. Higher air permeability can lead to higher levels of polycyclic aromatic hydrocarbons (PAHs), such as B[a]P. The applicant does not provide smoke yields of B[a]P or any other PAHs, but all provided HPHCs are analytically equivalent

between the new and predicate products. Therefore, the change in air permeability in SE0016733.PD1 does not cause the new products to raise different questions of public health.

Therefore, the differences in characteristics between the new and corresponding predicate products do not cause the new products to raise different questions of public health from a toxicology perspective.

4. ENVIRONMENTAL DECISION

The final environmental review found that the applicant did not provide sufficient market volume information for SE0016733.PD1, SE0017458.PD1, and SE0017587.PD1. Additionally, the applicant did not specify the marketing intention for the corresponding predicate products if the new products receive marketing orders. Therefore, additional information is needed to determine whether to prepare an Environmental Impact Statement (EIS) or Finding of No Significant Impact (FONSI) for SE0016733.PD1, SE0017458.PD1, and SE0017587.PD1.

For SE0016734.PD1, SE0016735.PD2, and SE0016736.PD2, a FONSI was signed by Luis Valerio, Ph.D. on June 8, 2022. The FONSI was supported by an environmental assessment prepared by FDA on June 6, 2022.

5. CONCLUSION AND RECOMMENDATION

The new and the predicate products have the following characteristics:

Chemistry evaluation complete:

- Ingredients:
  - SE0016733.PD1: quantity of (b)(4) (↓40%, (b)(mg/roll)
  - SE0016734.PD1-SE0016736.PD2, SE0017458.PD1, and SE0017587.PD1: Minimal ingredient differences

- Container Closure System:
  - SE0016733.PD1 and SE0017587.PD1: quantity changes

- Analytically equivalent increased HPHCs:
  - SE0016733.PD1: Acetaldehyde (↑7%, 133 µg/cig), Acrolein (↑10%, 14 µg/cig), Crotonaldehyde (↑5%, 4.2 µg/cig), and Formaldehyde (↑6%, 7 µg/cig)

Engineering evaluation complete:

- SE0016733.PD1: paper length (↓40%) and watermarked paper air permeability (↑37%)
- SE0016735.PD2 and SE0016736.PD2: paper tip length (↓34%) and paper tip width (↑7%)
- SE0017458.PD1 and SE17587.PD1: pre-rolled cone paper tip length (↑17%) for the new products compared to pre-rolled cylindrical paper tip for the predicate product

Toxicology evaluation complete:

- SE0016733.PD1: watermarked paper air permeability (↑37%)
- SE0016733.PD1: quantity of (b)(4) (↓40%, (b) mg/roll)

The new products have the following differences compared to the corresponding grandfathered products:

Engineering evaluation complete:

- SE0017458.PD1 and SE17587.PD1: pre-rolled cone paper tip length (↑17%) for the new products compared to pre-rolled cylindrical paper tip for the grandfathered product

I concur with the conclusions of all the scientific reviews that the applicant has demonstrated that these differences in characteristics do not cause the new products to raise different questions of public health as described in Section 3.1-3.3 above. The difference in container closure system in SE0016733.PD1, the identical CCS in SE0016734.PD1, SE0016735.PD2, SE0016736.PD2, and SE0017458.PD1, minimal ingredient differences in all SE Reports, and package quantity differences in SE0016733.PD1 (decreased roll length) and SE0017587.PD1 (increased number of tips) do not cause the new products to raise different questions of public health. The increased watermarked paper air permeability in the new products in SE0016733.PD1 does not cause the new products to raise different questions of public health because all mainstream smoke yields in the new and predicate products were analytically equivalent. The applicant did not provide MSS yields for the new and predicate products in SE0016734.PD1, SE0016735.PD2, SE0016736.PD2, SE0017458.PD1, and SE0017587.PD1 and the GF products in SE0017458.PD1 and SE0017587.PD1. Since the tip dimensions for the new and predicate products in SE0016734.PD1 are identical, the ingredient differences are minimal, and the product is not combusted during smoking, the lack of MSS for the new and predicate products in SE0016734.PD1 does not cause the new products to raise different questions of public health. In SE0016735.PD2 and SE0016736.PD2, the tip width is increased in the new products and the length is decreased. These differences would result in a shorter tobacco column with a decreased diameter if the same size rolling paper is used. This would result in less tobacco in the hand-rolled cigarette using the new products. Therefore, the lack of MSS for the new and predicate products in SE0016735.PD2 and SE0016736.PD2 does not cause the new products to raise different questions of public health. The new products in SE0017458.PD1 and SE0017587.PD1 are pre-rolled cone paper tips while the predicate and GF products are pre-rolled cylindrical paper tips. The new products are 17% longer, which would result in a shorter tobacco rod in the new product when the paper tips are assembled using the same size RYO rolling paper. Due to the variability in the way the tips may be rolled, the similar paper area, and the fact that the products are not combusted during smoking, the lack of MSS for the new, predicate and GF products in SE0017458.PD1 and SE0017587.PD1 does not cause the new products to raise different questions of public health. Therefore, the differences in characteristics between the new and corresponding predicate products do not cause the new products to raise different questions of public health.

The predicate products in SE0016733.PD1-SE0016736.PD2 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).

Some of the predicate products (SE0017458.PD1 and SE0017587.PD1) were previously determined to be substantially equivalent by FDA, as identified in Appendix A of this review. Where an applicant supports a showing of SE by comparing the new product to a product that FDA previously found SE, in order to issue an SE order, FDA must find that the new product is substantially equivalent to a product commercially marketed in the United States as of February 15, 2007 (see section 910(a)(2)(A)(i)(I) of the FD&C Act). No differences in characteristics between the new product and the product commercially marketed in the United States as of February 15, 2007, raise different questions of public health.

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. FDA examined the environmental effects of finding these new products substantially equivalent and made a FONSI for the new products in SE0016734.PD1, SE0016735.PD2, and SE0016736.PD2.

For SE0016733.PD1, SE0017458.PD1, and SE0017587.PD1, FDA examined the environmental effects of finding these new products substantially equivalent and found additional information is necessary to determine the impact of the action. Without this information, FDA is precluded from issuing an SE order.

An Environmental Information Request letter should be issued requesting the following information:

1. All your SE Reports lack information regarding the market volume and marketing intention of the predicate products after receiving marketing authorizations for the new products. Marketing information is used to quantitatively assess the environmental impact of manufacturing, use, and disposal of the new products as compared to the predicate products. Provide the following information:

    a. Clearly state if the predicate products for SE0016733.PD1, SE0017458.PD1, and SE0017587.PD1 will be simultaneously marketed in the United States if the new products receive marketing authorizations and if so, provide the current, first- and fifth-year market volumes and market volume projections for the predicate products, in their indicated units of measure, in the provided Table. Note any information you deem confidential so that it can be placed in a confidential appendix to the public environmental assessment document.

Market Volumes and Market Projections for New and Predicate Products

STN	Unit	Current Year		First-Year		Fifth-Year	
		New	Predicate	New	Predicate	New	Predicate
SE0016733.PD1	Paper Rolls[2]	(b)(4)					
SE0017458.PD1	Paper Tips						
SE0017587.PD1	Paper Tips						

If the applicant adequately responds to the request and an EIS or FONSI is completed, SE order letters should be issued for the new products in SE0016733.PD1, SE0017458.PD1, and SE0017587.PD1.

[2] Rolls: Each roll is 3000 mm long and 70 mm length equates to 1 RYO cigarette; 1-roll is ~ 42 cigarettes.

6. APPENDICES

Appendix A. New and predicate products

Common Attributes		
Applicant	BBK Tobacco & Foods LLP dba HBI International	
Product manufacturer	BBK Tobacco & Foods LLP dba HBI International	
Product category	Roll-Your-Own Tobacco Products	
Attributes	**New Product**	**Predicate Product**
STN.PD#	**SE0016733.PD1**	**Not Applicable (N/A)**
Submission date	June 22, 2020	N/A
Receipt date	June 22, 2020	N/A
Product subcategory	Rolling Paper	Rolling Paper
Product name	RAW CLASSIC KING SIZE ROLLS[a]	ELEMENTS ROLLS ULTRA THIN 1 ½ KS[a]
Eligibility status	N/A	Grandfathered
Package type	Cardboard Box	Plastic Box
Package quantity	1 Roll	1 Roll
Characterizing flavor	None	None
Length	3000 mm	5000 mm
Width	54 mm	54 mm
Nicotine source[b]	None	None
Additional property	Off-White "RAW" watermark	Off-White "HBI" watermark
STN.PD#	**SE0016734.PD1**	**N/A**
Submission date	June 22, 2020	N/A
Receipt date	June 22, 2020	N/A
Product subcategory	Paper Tip	Paper Tip
Product name	WIZ KHALIFA TIPS[a]	ELEMENTS TIPS REGULAR[a,c]
Eligibility status	N/A	Grandfathered
Package type	Book	Book
Package quantity	50 Tips	50 Tips
Characterizing flavor	None	None
Length	58.5 mm	58.5 mm
Width	17.5 mm	17.5 mm
Nicotine source[b]	None	None
Additional property	Off-white Perforated	White Non-perforated

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

[b] Effective April 14, 2022, FDA's authority to regulate tobacco products was extended to include tobacco products containing nicotine from any source. As such, nicotine source is considered a required property for unique identification. https://www.congress.gov/bill/117th-congress/house-bill/2471

[c] In 2007, the name of predicate was ELEMENTS NON-PERFORATED TIPS, but then in 2011 it was renamed to ELEMENTS TIPS REGULAR

STN.PD#	**SE0016735.PD2**	**N/A**
Submission date	June 22, 2020	N/A
Receipt date	June 22, 2020	N/A
Product subcategory	Paper Tip	Paper Tip
Product name	RAW ORGANIC HEMP CONNOISSEUR 1 ¼ (WITH TIPS) [a]	RAW TIPS ORIGINAL[a]
Eligibility status	N/A	Grandfathered
Package type	Book	Book
Package quantity	50 Tips	50 Tips
Characterizing flavor	None	None
Length	39 mm	59.5 mm
Width	19 mm	17.7 mm
Nicotine source[b]	None	None
STN.PD#	**SE0016736.PD2**	**N/A**
Submission date	June 22, 2020	N/A
Receipt date	June 22, 2020	N/A
Product subcategory	Paper Tip	Paper Tip
Product name	RAW ORGANIC HEMP ARTESANO 1 ¼ WITH TRAY + PAPERS + TIPS[a]	RAW TIPS ORIGINAL[a,a]
Eligibility status	N/A	Grandfathered
Package type	Book	Book
Package quantity	50 Tips	50 Tips
Characterizing flavor	None	None
Length	39 mm	59.5 mm
Width	19 mm	17.7 mm
Nicotine source[b]	None	None
Additional property	Perforation lines	N/A
STN.PD#	**SE0017458.PD1**	**SE0015554**
Submission date	August 24, 2020	November 4, 2019
Receipt date	August 24, 2020	November 4, 2019
Product subcategory	Paper Tip	Paper Tip
Product name	RAW PERFECTO PRE-ROLLED CONE TIPS – 21 CT[a]	ELEMENTS PRE-ROLLED TIPS[a]
Eligibility status	N/A	Previously found SE
Package type	Tray slider box	Tray slider box
Package quantity	21 Tips	21 Tips
Characterizing flavor	None	None
Length	21 mm	58 mm
Width	N/A	18 mm
Nicotine source[b]	None	None

[a] In 2007, the predicate name was RAW UNBLEACHED TIPS and is described on the invoices as RAW #773 UNREFINED ROLL-UP TIPS 50/BOX

Additional property	White Red "RAW" logo Pre-rolled Perforations	White Blue "ELEMENTS" logo Pre-rolled
STN.PD#	**SE0017587.PD1**	**SE0015554**
Submission date	August 24, 2020	November 4, 2019
Receipt date	August 24, 2020	November 4, 2019
Product subcategory	Paper Tip	Paper Tip
Product name	RAW PERFECTO PRE-ROLLED CONE TIPS – 100 CT[a]	ELEMENTS PRE-ROLLED TIPS[a]
Eligibility status	N/A	Previously found SE
Package type	Box	Tray slider box
Package quantity	100 Tips	21 Tips
Characterizing flavor	None	None
Length	21 mm	58 mm
Width	N/A	18 mm
Nicotine source[b]	None	None
Additional property	Beige Red "RAW" logo Pre-rolled Perforations	White Blue "ELEMENTS" logo Pre-rolled

Appendix B. Amendments

Submission Date	Receipt Date	Amendment	Applications being amended	Reviewed	Brief Description
May 20, 2021	May 20, 2021	SE0024631	SE0016735.PD2, SE0016736.PD2	Yes	Response to May 18, 2021, FDA Information Request