



Technical Project Lead (TPL) Review: SE Reports Submitted by Atlas Pacific Manufacturing

SE0011286: RYOT King
SE0011288: Wiz Khalifa King
SE0011292: Blue Phoenix King
SE0011299: Mimosa King
SE0011301: Righteous Roots Movement King
SE0011302: Bocomo Bay King
SE0011303: The Grow Show King
SE0011304: Desert Distribution Box King
SE0011307: Slightly Stoopid Seedless King
SE0011313: Cadillac KS King
SE0011315: Prez Paper Co. KS King
SE0011316: Hold Fast King
SE0011317: Spike KS King
SE0011318: My Monster Glass King
SE0011319: Giggles King
SE0011323: Burnton King
SE0011325: Southern Wholesalers King
SE0011329: Artsy Fartsy WBAI King
SE0011330: Humboldt Fire King
SE0011332: Kings of Cali King
SE0011334: The Gliffics King
SE0011337: Str8bent King
SE0011339: Levitation Project King
SE0011341: POLISH King
SE0011342: Yes Now King
SE0011343: Humboldt Clothing King
SE0011344: Your Grow King
SE0011345: Glass Gripper King
SE0011346: Feeling Groovy King
SE0011348: Essential King
SE0011349: Chesterfield Glass King
SE0011350: Blue Collar King
SE0011351: Plur King
SE0011352: Doobies King
SE0011353: Spectrum Labs King
SE0011355: Krutch KS King
SE0011358: BandMerch MMJ King
SE0011359: Gas Pipe King
SE0011360: Casa De Los Muertos King
SE0011361: Kung Fu King

SE0011364: Galindo King	
SE0011365: VLG King	
SE0011366: Polar World King	
SE0011367: Mountain Man Products King	
SE0011368: Capstan King	
SE0011369: All Seasons Gardening King	
SE0011370: Strippies King	
SE0011372: GRN Glassworks KS King	
SE0011374: Sohiyo King	
SE0011375: Rob Shop King	
SE0011376: Slightly Stoopid King	
SE0011377: Keep It Kush King	
SE0011380: Seattle King	
SE0011382: Purple Haze King	
SE0011387: Blackbird King	
SE0011388: Karma King	
SE0011389: Bud Life KS King	
SE0011390: Sampson King	
SE0011391: YOLO King	
SE0011392: KANHAI King	
SE0011394: Crazy Bill's King	
SE0011395: Gaia King	
SE0011396: Cloud 9 King	
SE0011403: Mystery Weed Shopper King	
SE0011404: Schwag King	
SE0011405: Dollhouse King	
SE0011406: 4twentycard King	
SE0011407: Fatbol King	
SE0011410: Higher Path King	
SE0011414: Eagle Valley King	
SE0011418: Herbal Solutions King	
SE0011422: Healing Green King	
Package Type	Booklet
Package Quantity	33 papers
Length	107 mm
Width	44 mm
Characterizing Flavor	None
SE0011475: RYOT 1 1/4	
SE0011477: Wiz Khalifa 1 1/4	
SE0011481: Blue Phoenix 1 1/4	
SE0011485: Joe Moorhead 1 1/4	
SE0011488: Mimosa 1 1/4	
SE0011490: Righteous Roots Movement 1 1/4	
SE0011491: Bocomo Bay 1 1/4	
SE0011492: The Grow Show 1 1/4	
SE0011493: Desert Distribution Box 1 1/4	

SE0011496: Slightly Stoopid Seedless 1 1/4
SE0011502: Cadillac 1 1/4
SE0011504: Prez Paper Co. 1 1/4
SE0011505: Hold Fast 1 1/4
SE0011506: Spike 1 1/4
SE0011507: My Monster Glass 1 1/4
SE0011508: Giggles 1 1/4
SE0011511: Burnton 1 1/4
SE0011513: Southern Wholesalers 1 1/4
SE0011517: Artsy Fartsy WBAI 1 1/4
SE0011518: Humboldt Fire 1 1/4
SE0011520: Kings of Cali 1 1/4
SE0011522: The Gliffics 1 1/4
SE0011524: Str8bent 1 1/4
SE0011526: Levitation Project 1 1/4
SE0011528: POLISH 1 1/4
SE0011529: Yes Now 1 1/4
SE0011530: Humboldt Clothing 1 1/4
SE0011531: Your Grow 1 1/4
SE0011532: Glass Gripper 1 1/4
SE0011533: Feeling Groovy 1 1/4
SE0011535: Essential 1 1/4
SE0011536: Chesterfield Glass 1 1/4
SE0011537: Blue Collar 1 1/4
SE0011538: Plur 1 1/4
SE0011539: Doobies 1 1/4
SE0011540: Spectrum Labs 1 1/4
SE0011542: Krutch 1 1/4
SE0011545: BandMerch MMJ 1 1/4
SE0011546: Gas Pipe 1 1/4
SE0011547: Casa De Los Muertos 1 1/4
SE0011548: Kung Fu 1 1/4
SE0011551: Galindo 1 1/4
SE0011552: VLG 1 1/4
SE0011553: Polar World 1 1/4
SE0011554: Mountain Man Products 1 1/4
SE0011555: Capstan 1 1/4
SE0011556: All Seasons Gardening 1 1/4
SE0011557: Strippies 1 1/4
SE0011559: GRN Glassworks 1 1/4
SE0011560: White Rhino 1 1/4
SE0011561: Sohiyo 1 1/4
SE0011562: Rob Shop 1 1/4
SE0011564: Keep It Kush 1 1/4
SE0011565: Bud Life 1 1/4
SE0011567: Seattle 1 1/4

SE0011569: Purple Haze 1 1/4	
SE0011570: Gliffics 1 1/4	
SE0011574: Blackbird 1 1/4	
SE0011575: Karma 1 1/4	
SE0011577: Sampson 1 1/4	
SE0011578: YOLO 1 1/4	
SE0011579: KANHAI 1 1/4	
SE0011581: Crazy Bill's 1 1/4	
SE0011582: Gaia 1 1/4	
SE0011583: Cloud 9 1 1/4	
SE0011590: Mystery Weed Shopper 1 1/4	
SE0011591: Slightly Stoopid 1 1/4	
SE0011592: Schwag 1 1/4	
SE0011593: Dollhouse 1 1/4	
SE0011594: 4twentycard 1 1/4	
SE0011595: Fatbol 1 1/4	
SE0011598: Higher Path 1 1/4	
SE0011602: Eagle Valley 1 1/4	
SE0011606: Herbal Solutions 1 1/4	
SE0011610: Healing Green 1 1/4	
Package Type	Booklet
Package Quantity	33 papers
Length	78 mm
Width	44 mm
Characterizing Flavor	None
Common Attributes of SE Reports	
Applicant	Atlas Pacific Manufacturing
Report Type	Regular Same Characteristics SE Report
Product Category	Roll-Your-Own Tobacco
Product Sub-Category	Rolling Paper
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Colleen K. Rogers, Ph.D.
Deputy 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)

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

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products to compare with the new tobacco products below:

SE0011286: RYOT King
SE0011288: Wiz Khalifa King
SE0011292: Blue Phoenix King
SE0011299: Mimosa King
SE0011301: Righteous Roots Movement King
SE0011302: Bocomo Bay King
SE0011303: The Grow Show King
SE0011304: Desert Distribution Box King
SE0011307: Slightly Stoopid Seedless King
SE0011313: Cadillac KS King
SE0011315: Prez Paper Co. KS King
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SE0011332: Kings of Cali King
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SE0011337: Str8bent King
SE0011339: Levitation Project King
SE0011341: POLISH King
SE0011342: Yes Now King
SE0011343: Humboldt Clothing King
SE0011344: Your Grow King
SE0011345: Glass Gripper King
SE0011346: Feeling Groovy King
SE0011348: Essential King
SE0011349: Chesterfield Glass King
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SE0011353: Spectrum Labs King
SE0011355: Krutch KS King
SE0011358: BandMerch MMJ King
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SE0011360: Casa De Los Muertos King
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SE0011365: VLG King	
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SE0011367: Mountain Man Products King	
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SE0011369: All Seasons Gardening King	
SE0011370: Strippies King	
SE0011372: GRN Glassworks KS King	
SE0011374: Sohiyo King	
SE0011375: Rob Shop King	
SE0011376: Slightly Stoopid King	
SE0011377: Keep It Kush King	
SE0011380: Seattle King	
SE0011382: Purple Haze King	
SE0011387: Blackbird King	
SE0011388: Karma King	
SE0011389: Bud Life KS King	
SE0011390: Sampson King	
SE0011391: YOLO King	
SE0011392: KANHAI King	
SE0011394: Crazy Bill's King	
SE0011395: Gaia King	
SE0011396: Cloud 9 King	
SE0011403: Mystery Weed Shopper King	
SE0011404: Schwag King	
SE0011405: Dollhouse King	
SE0011406: 4twentycard King	
SE0011407: Fatbol King	
SE0011410: Higher Path King	
SE0011414: Eagle Valley King	
SE0011418: Herbal Solutions King	
SE0011422: Healing Green King	
Product Name	Chris Hill (King)
Package Type	Booklet
Package Quantity	33 papers
Length	107 mm
Width	44 mm
Characterizing Flavor	None
SE0011475: RYOT 1 1/4	
SE0011477: Wiz Khalifa 1 1/4	
SE0011481: Blue Phoenix 1 1/4 1 1/4	
SE0011485: Joe Moorhead 1 1/4	
SE0011488: Mimosa 1 1/4	
SE0011490: Righteous Roots Movement 1 1/4	
SE0011491: Bocomo Bay 1 1/4	
SE0011492: The Grow Show 1 1/4	

SE0011493: Desert Distribution Box 1 1/4
SE0011496: Slightly Stoopid Seedless 1 1/4
SE0011502: Cadillac 1 1/4
SE0011504: Prez Paper Co. 1 1/4
SE0011505: Hold Fast 1 1/4
SE0011506: Spike 1 1/4
SE0011507: My Monster Glass 1 1/4
SE0011508: Giggles 1 1/4
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SE0011570: Gliffics 1 1/4	
SE0011574: Blackbird 1 1/4	
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SE0011577: Sampson 1 1/4	
SE0011578: YOLO 1 1/4	
SE0011579: KANHAI 1 1/4	
SE0011581: Crazy Bill's 1 1/4	
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SE0011593: Dollhouse 1 1/4	
SE0011594: 4twentycard 1 1/4	
SE0011595: Fatbol 1 1/4	
SE0011598: Higher Path 1 1/4	
SE0011602: Eagle Valley 1 1/4	
SE0011606: Herbal Solutions 1 1/4	
SE0011610: Healing Green 1_14 1 1/4	
Product Name	Chris Hill (1 1/4)
Package Type	Booklet
Package Quantity	33 papers
Length	78 mm
Width	44 mm
Characterizing Flavor	None

The predicate tobacco products are roll-your-own tobacco rolling papers manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On April 3, 2015, FDA received 147 Same Characteristics Regular SE Reports from the applicant. On May 4, 2015, FDA requested that the applicant provide information needed to uniquely identify the new and predicate tobacco product as well as revised certification statements. On May 11, 2015, the applicant submitted amendment SE0011754 with the requested information. On May 26, 2015, FDA requested that the applicant provide environmental assessment information. The applicant submitted amendment SE0011907 on June 2, 2015, and amendment SE0011970 on June 8, 2015, with the requested information. On June 30, 2015, FDA sent an Advice/Information Request letter requesting additional environmental assessment information. On July 30, 2015, the applicant submitted amendment SE0012243 with the requested information.

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for these SE Reports.

2. REGULATORY REVIEW

Regulatory reviews were completed by the following regulatory health project managers (RHPMs):

- Angela Brown on April 15, 2015, and April 16, 2015
- Cecilia Robinson on April 15, 2015
- Grace Kaiyuan on April 15, 2015
- Kendric Neely on April 14, 2015, April 15, 2015, April 16, 2015, June 26, 2015, August 19, 2015, and August 20, 2015
- Samuel Motto on August 17, 2015, and August 20, 2015

The final reviews conclude that each SE Report includes all of the information recommended in the final SE FAQ guidance document for a Same Characteristics SE Report:

1. The SE Reports are identified as “Same Characteristics SE Reports.”
2. The new tobacco products are uniquely identified.
3. The predicate tobacco products are uniquely identified.
4. There is a statement indicating that the applicant intends to market both the new and predicate tobacco products.
5. An Environmental Assessment was provided.
6. There is a statement indicating that the applicant will make a health information summary available upon request by any person in accordance with section 910(a)(4) of the FD&C Act.
7. There is a statement explaining the applicant’s actions to comply with any applicable standards under section 907 of the FD&C Act.
8. The SE Reports included an adequate certification statement, and the statement is signed by a responsible official who is authorized to act on behalf of the company.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews 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 reviews dated June 12, 2015, and June 15, 2015, conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products are eligible predicate tobacco products.

OCE also completed a review 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 review dated October 14, 2015, concludes that the new tobacco products are in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

Scientific review was not initiated by the Office of Science (OS) because the characteristics of the new and corresponding predicate tobacco products are the same (i.e., the new and predicate products have identical characteristics). Therefore, scientific review is unnecessary.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on October 6, 2015. The FONSI was supported by an environmental assessment prepared by FDA on October 5, 2015.

6. CONCLUSION AND RECOMMENDATION

In all of the SE Reports, the product names differ between the new and corresponding predicate tobacco products, but the characteristics of the new and corresponding predicate tobacco products are the same (i.e., identical characteristics). The SE Reports include all of the information needed by FDA to make an SE determination.

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).

All of the new tobacco 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 tobacco products substantially equivalent and made a finding of no significant impact.

SE order letters should be issued for the new tobacco products in SE0011286, SE0011288, SE0011292, SE0011299, SE0011301-SE0011304, SE0011307, SE0011313, SE0011315 – SE0011319, SE0011323, SE0011325, SE0011329, SE0011330, SE0011332, SE0011334, SE0011337, SE0011339, SE0011341 – SE0011346, SE0011348-SE0011353, SE0011355, SE0011358 – SE0011361, SE0011364-SE0011370, SE0011372, SE0011374 – SE0011377, SE0011380, SE0011382, SE0011387 – SE0011392, SE0011394 – SE0011396, SE0011403 – SE0011407, SE0011410, SE0011414,

SE0011418, SE0011422, SE0011475, SE0011477, SE0011481, SE0011485, SE0011488, SE0011490 – SE0011493, SE0011496, SE0011502, SE0011504 – SE0011508, SE0011511, SE0011513, SE0011517, SE0011518, SE0011520, SE0011522, SE0011524, SE0011526, SE0011528 – SE0011533, SE0011535 – SE0011540, SE0011542, SE0011545 – SE0011548, SE0011551 – SE0011557, SE0011559 – SE0011562, SE0011564, SE0011565, SE0011567, SE0011569, SE0011570, SE0011574, SE0011575, SE0011577 – SE0011579, SE0011581 – SE0011583, SE0011590 – SE0011595, SE0011598, SE0011602, SE0011606, and SE0011610 as identified on the cover page of this review.