



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

**SE0011287: Tobacco Road King**  
**SE0011289: Hawaiian Holy Smokes-Sea Life King**  
**SE0011291: Hawaiian Holy Smokes-Island King**  
**SE0011296: Joe Moorhead KS King**  
**SE0011298: Hawaiian Holy Smoke-Rasta KS King**  
**SE0011305: Grooveshark King**  
**SE0011308: Hawaiian Holy Smoke-Tiki KS King**  
**SE0011309: North Bowl King**  
**SE0011310: Mr. Eddie's Headies KS King**  
**SE0011312: Headdies KS King**  
**SE0011321: Brennan's King**  
**SE0011324: Piece of Mind King**  
**SE0011326: Free Spirits King**  
**SE0011327: Peace Pipe King**  
**SE0011328: Ronin King**  
**SE0011333: HOTH King**  
**SE0011338: The Tobacco Stop King**  
**SE0011347: ROLLIT King**  
**SE0011354: Hawaiian Cowboy King**  
**SE0011357: Pipe World King**  
**SE0011362: Tex Star Smoke King**  
**SE0011363: Filters Smokeshop King**  
**SE0011373: White Rhino KS King**  
**SE0011379: Smokeys King**  
**SE0011381: Cocky King**  
**SE0011383: Gliffics King**  
**SE0011384: SMOKIN J'S King**  
**SE0011385: Puff n Stuff King**  
**SE0011386: Cinderbox King**  
**SE0011393: Modern Primitives King**  
**SE0011397: Rollerz King**  
**SE0011398: High Times King**  
**SE0011399: Munchies 420 King**  
**SE0011400: Smokin' Money King**  
**SE0011401: Stuff Stoners Like King**  
**SE0011402: LUCCI King**  
**SE0011408: Castaways King**  
**SE0011409: Clearly Faded King**  
**SE0011412: Joe's East King**  
**SE0011413: Smoke Cartel King**

**SE0011416: Rocky Mountain King**  
**SE0011417: Nine Mile King**  
**SE0011419: Off Ya Tree King**  
**SE0011421: T-Zone KS King**  
**SE0011423: Bonez King**  
**SE0011468: Covelo Gold King**  
**SE0011469: Dank Depot King**  
**SE0011471: Kush Water King**  
**SE0011473: Proverde Labs King**  
**SE0011474: Thiessen Law King**  
**SE0011469 Dank Depot King**  
**SE0011471 Kush Water King**  
**SE0011473 Proverde Labs King**  
**SE0011474 Thiessen Law King**  
**SE0011476 Tobacco Road 1 1/4**  
**SE0011478 Hawaiian Holy Smokes-Sea Life 1 1/4**  
**SE0011480 Hawaiian Holy Smokes-Island 1 1/4**  
**SE0011487 Hawaiian Holy Smoke-Rasta 1 1/4**  
**SE0011494 Grooveshark 1 1/4**  
**SE0011497 Hawaiian Holy Smoke-Tiki 1 1/4**  
**SE0011498 North Bowl 1 1/4**  
**SE0011499 Mr. Eddie's Headies 1 1/4**  
**SE0011501 Headdies 1 1/4**  
**SE0011509 Brennan's 1 1/4**  
**SE0011512 Piece of Mind 1 1/4**  
**SE0011514 Free Spirits 1 1/4**  
**SE0011515 Peace Pipe 1 1/4**  
**SE0011516 Ronin 1 1/4**  
**SE0011521 HOTH 1 1/4**  
**SE0011525 The Tobacco Stop 1 1/4**  
**SE0011534 ROLLIT 1 1/4**  
**SE0011541 Hawaiian Cowboy 1 1/4**  
**SE0011544 Pipe World 1 1/4**  
**SE0011549 Tex Star Smoke 1 1/4**  
**SE0011550 Filters Smokeshop 1 1/4**  
**SE0011566 Smokeys 1 1/4**  
**SE0011568 Cocky 1 1/4**  
**SE0011571 SMOKIN J'S 1 1/4**  
**SE0011572 Puff n Stuff 1 1/4**  
**SE0011573 Cinderbox 1 1/4**  
**SE0011576 Perfect Place 1 1/4**  
**SE0011580 Modern Primitives 1 1/4**  
**SE0011584 Rollerz 1 1/4**  
**SE0011585 High Times 1 1/4**  
**SE0011586 Munchies 420 1 1/4**  
**SE0011587 Smokin' Money 1 1/4**

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| <b>SE0011588 Stuff Stoners Like 1 1/4</b>          |  |
| <b>SE0011589 LUCCI 1 1/4</b>                       |  |
| <b>SE0011596 Castaways 1 1/4</b>                   |  |
| <b>SE0011597 Clearly Faded 1 1/4</b>               |  |
| <b>SE0011600 Joe's East 1 1/4</b>                  |  |
| <b>SE0011601 Smoke Cartel 1 1/4</b>                |  |
| <b>SE0011603 Adam Marsh 1 1/4</b>                  |  |
| <b>SE0011604 Rocky Mountain 1 1/4</b>              |  |
| <b>SE0011605 Nine Mile 1 1/4</b>                   |  |
| <b>SE0011607 Off Ya Tree 1 1/4</b>                 |  |
| <b>SE0011608 Victor Attorney for Freedom 1 1/4</b> |  |
| <b>SE0011609 T-Zone 1 1_4 1 1/4</b>                |  |
| <b>SE0011611 Bonez 1 1/4</b>                       |  |
| <b>SE0011656 Covelo Gold 1 1/4</b>                 |  |
| <b>SE0011657 Dank Depot 1 1/4</b>                  |  |
| <b>SE0011659 Kush Water 1 1/4</b>                  |  |
| <b>SE0011661 Proverde Labs 1 1/4</b>               |  |
| <b>SE0011662 Thiessen Law 1 1/4</b>                |  |
| Package Type                                       | Booklet                                |
| Package Quantity                                   | 33 papers                              |
| Length   | 107 mm                                 |
| Width  | 44 mm                                  |
| Characterizing Flavor                              | None                                   |
|  |  |
| Package Type                                       | Booklet                                |
| Package Quantity                                   | 33 papers                              |
| Length   | 78 mm                                  |
| Width  | 44 mm                                  |
| Characterizing Flavor                              | None                                   |
| <b>Common Attributes of SE Reports</b>             |  |
| Applicant  | Atlas Pacific Manufacturing            |
| Report Type  | Regular Same Characteristics SE Report |
| Product Category                                   | Roll-Your-Own Tobacco                  |
| Product Sub-Category                               | Rolling Paper                          |
| <b>Recommendation</b>                              |  |
| Issue Substantially Equivalent (SE) orders.        |  |

**Technical Project Lead (TPL):**

Matthew R. Holman, Ph.D.  
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 product below:

**SE0011287: Tobacco Road King**  
**SE0011289: Hawaiian Holy Smokes-Sea Life King**  
**SE0011291: Hawaiian Holy Smokes-Island King**  
**SE0011296: Joe Moorhead KS King**  
**SE0011298: Hawaiian Holy Smoke-Rasta KS King**  
**SE0011305: Grooveshark King**  
**SE0011308: Hawaiian Holy Smoke-Tiki KS King**  
**SE0011309: North Bowl King**  
**SE0011310: Mr. Eddie's Headies KS King**  
**SE0011312: Headdies KS King**  
**SE0011321: Brennan's King**  
**SE0011324: Piece of Mind King**  
**SE0011326: Free Spirits King**  
**SE0011327: Peace Pipe King**  
**SE0011328: Ronin King**  
**SE0011333: HOTH King**  
**SE0011338: The Tobacco Stop King**  
**SE0011347: ROLLIT King**  
**SE0011354: Hawaiian Cowboy King**  
**SE0011357: Pipe World King**  
**SE0011362: Tex Star Smoke King**  
**SE0011363: Filters Smokeshop King**  
**SE0011373: White Rhino KS King**  
**SE0011379: Smokeys King**  
**SE0011381: Cocky King**  
**SE0011383: Gliffics King**  
**SE0011384: SMOKIN J'S King**  
**SE0011385: Puff n Stuff King**  
**SE0011386: Cinderbox King**  
**SE0011393: Modern Primitives King**  
**SE0011397: Rollerz King**  
**SE0011398: High Times King**  
**SE0011399: Munchies 420 King**  
**SE0011400: Smokin' Money King**  
**SE0011401: Stuff Stoners Like King**  
**SE0011402: LUCCI King**  
**SE0011408: Castaways King**  
**SE0011409: Clearly Faded King**  
**SE0011412: Joe's East King**  
**SE0011413: Smoke Cartel King**

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|--|-------------------|
| <b>SE0011416: Rocky Mountain King</b>                |                   |
| <b>SE0011417: Nine Mile King</b>                     |                   |
| <b>SE0011419: Off Ya Tree King</b>                   |                   |
| <b>SE0011421: T-Zone KS King</b>                     |                   |
| <b>SE0011423: Bonez King</b>                         |                   |
| <b>SE0011468: Covelo Gold King</b>                   |                   |
| <b>SE0011469: Dank Depot King</b>                    |                   |
| <b>SE0011471: Kush Water King</b>                    |                   |
| <b>SE0011473: Proverde Labs King</b>                 |                   |
| <b>SE0011474: Thiessen Law King</b>                  |                   |
| <b>SE0011469 Dank Depot King</b>                     |                   |
| <b>SE0011471 Kush Water King</b>                     |                   |
| <b>SE0011473 Proverde Labs King</b>                  |                   |
| <b>SE0011474 Thiessen Law King</b>                   |                   |
| Product Name   | Chris Hill (King) |
| Package Type   | Booklet           |
| Package Quantity                                     | 33 papers         |
| Length   | 107 mm            |
| Width  | 44 mm             |
| Characterizing Flavor                                | None              |
| <b>SE0011476 Tobacco Road 1 1/4</b>                  |                   |
| <b>SE0011478 Hawaiian Holy Smokes-Sea Life 1 1/4</b> |                   |
| <b>SE0011480 Hawaiian Holy Smokes-Island 1 1/4</b>   |                   |
| <b>SE0011487 Hawaiian Holy Smoke-Rasta 1 1/4</b>     |                   |
| <b>SE0011494 Grooveshark 1 1/4</b>                   |                   |
| <b>SE0011497 Hawaiian Holy Smoke-Tiki 1 1/4</b>      |                   |
| <b>SE0011498 North Bowl 1 1/4</b>                    |                   |
| <b>SE0011499 Mr. Eddie's Headies 1 1/4</b>           |                   |
| <b>SE0011501 Headdies 1 1/4</b>                      |                   |
| <b>SE0011509 Brennan's 1 1/4</b>                     |                   |
| <b>SE0011512 Piece of Mind 1 1/4</b>                 |                   |
| <b>SE0011514 Free Spirits 1 1/4</b>                  |                   |
| <b>SE0011515 Peace Pipe 1 1/4</b>                    |                   |
| <b>SE0011516 Ronin 1 1/4</b>                         |                   |
| <b>SE0011521 HOTH 1 1/4</b>                          |                   |
| <b>SE0011525 The Tobacco Stop 1 1/4</b>              |                   |
| <b>SE0011534 ROLLIT 1 1/4</b>                        |                   |
| <b>SE0011541 Hawaiian Cowboy 1 1/4</b>               |                   |
| <b>SE0011544 Pipe World 1 1/4</b>                    |                   |
| <b>SE0011549 Tex Star Smoke 1 1/4</b>                |                   |
| <b>SE0011550 Filters Smokeshop 1 1/4</b>             |                   |
| <b>SE0011566 Smokeys 1 1/4</b>                       |                   |
| <b>SE0011568 Cocky 1 1/4</b>                         |                   |
| <b>SE0011571 SMOKIN J'S 1 1/4</b>                    |                   |
| <b>SE0011572 Puff n Stuff 1 1/4</b>                  |                   |
| <b>SE0011573 Cinderbox 1 1/4</b>                     |                   |

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|-----------------------|--|
| <b>SE0011576</b>      | <b>Perfect Place 1 1/4</b>               |
| <b>SE0011580</b>      | <b>Modern Primitives 1 1/4</b>           |
| <b>SE0011584</b>      | <b>Rollerz 1 1/4</b>                     |
| <b>SE0011585</b>      | <b>High Times 1 1/4</b>                  |
| <b>SE0011586</b>      | <b>Munchies 420 1 1/4</b>                |
| <b>SE0011587</b>      | <b>Smokin' Money 1 1/4</b>               |
| <b>SE0011588</b>      | <b>Stuff Stoners Like 1 1/4</b>          |
| <b>SE0011589</b>      | <b>LUCCI 1 1/4</b>                       |
| <b>SE0011596</b>      | <b>Castaways 1 1/4</b>                   |
| <b>SE0011597</b>      | <b>Clearly Faded 1 1/4</b>               |
| <b>SE0011600</b>      | <b>Joe's East 1 1/4</b>                  |
| <b>SE0011601</b>      | <b>Smoke Cartel 1 1/4</b>                |
| <b>SE0011603</b>      | <b>Adam Marsh 1 1/4</b>                  |
| <b>SE0011604</b>      | <b>Rocky Mountain 1 1/4</b>              |
| <b>SE0011605</b>      | <b>Nine Mile 1 1/4</b>                   |
| <b>SE0011607</b>      | <b>Off Ya Tree 1 1/4</b>                 |
| <b>SE0011608</b>      | <b>Victor Attorney for Freedom 1 1/4</b> |
| <b>SE0011609</b>      | <b>T-Zone 1 1_4 1 1/4</b>                |
| <b>SE0011611</b>      | <b>Bonez 1 1/4</b>                       |
| <b>SE0011656</b>      | <b>Covelo Gold 1 1/4</b>                 |
| <b>SE0011657</b>      | <b>Dank Depot 1 1/4</b>                  |
| <b>SE0011659</b>      | <b>Kush Water 1 1/4</b>                  |
| <b>SE0011661</b>      | <b>Proverde Labs 1 1/4</b>               |
| <b>SE0011662</b>      | <b>Thiessen Law 1 1/4</b>                |
| 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 (b)(4) 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. (b)(4)

(b)(4)



### **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 Kendric Neely on April 14, 2015, April 15, 2015, and June 26, 2015. The final review concludes 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.

The Office of Compliance and Enforcement (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 June 12, 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 June 26, 2015. The FONSI was supported by an environmental assessment prepared by FDA on June 26, 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 SE0011287, SE0011289, SE0011291, SE0011296, SE0011298, SE0011305, SE0011308-SE0011310, SE0011312, SE0011321, SE0011324, SE0011326, SE0011327, SE0011328, SE0011333, SE0011338, SE0011347, SE0011354, SE0011357, SE0011362, SE0011363, SE0011373, SE0011379, SE0011381, SE0011383-SE0011386, SE0011393, SE0011397- SE0011402, SE0011408, SE0011409, SE0011412, SE0011413, SE0011416-SE0011417, SE0011419-SE0011421, SE0011423, SE0011468, SE0011469, SE0011471, SE0011473, SE0011474, SE0011476, SE0011478, SE0011480, SE0011487, SE0011494, SE0011497-SE0011499, SE0011501, SE0011509, SE0011512, SE0011514-SE0011516, SE0011521, SE0011525, SE0011534, SE0011541, SE0011544, SE0011549, SE0011550, SE0011566, SE0011568, SE0011571-SE0011573, SE0011576, SE0011580, SE0011584- SE0011589, SE0011596, SE0011597, SE0011600, SE0011601, SE0011603 –SE0011605, SE0011607-SE0011609, SE0011611, SE0011656, SE0011657, SE0011659, SE0011661, SE0011662 as identified on the cover page of this review.