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## Technical Project Lead (TPL) Review:

**SE0002424-SE0002460, SE0002462,  
SE0002464-SE0002474, SE0002479-SE0002482,  
SE0002484, SE0002495-SE0002511,  
SE0002513-SE0002518, SE0002520-SE0002534, and  
SE0002541-SE0002546**

**SE0002424: Nine Dragons  
SE0002427: Cris2  
SE0002429: Kulture (008)<sup>1</sup>  
SE0002451: Treasure Chest  
SE0002453: Wiz Khalifa  
SE0002457: Whelan's  
SE0002458: Bocomo Bay (047)  
SE0002462: Gord's Smoke Shop  
SE0002465: Adrenalin Rush (054)  
SE0002468: H. Flyer  
SE0002469: Holy Smoke  
SE0002470: Tasty Puff  
SE0002471: Slightly Stoopid (061)  
SE0002480: Sky Dancer  
SE0002481: Smokin' J's (075)  
SE0002501: Kulture (095)  
SE0002506: South Union Bar and Grill  
SE0002509: Capitol Hemp (105)  
SE0002510: Aaron's Rock and Roll (106)  
SE0002511: Moderne Primitives (107)  
SE0002514: Krutch  
SE0002515: Paper Airplanes  
SE0002516: Waaves  
SE0002517: Ithaca Hemp (113)  
SE0002520: Spectrum Labs  
SE0002522: Bocomo Bay (118)  
SE0002523: Slightly Stoopid (119)  
SE0002524: Purple Haze  
SE0002528: Slug Magazine  
SE0002533: Mr. Eddies Headies  
SE0002534: Easy**

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<sup>1</sup> The product names identified in this section of the review reflect those provided by the applicant. However, the numbers in parentheses at the end of some product names are not actually part of the product names (e.g., "(008)") and should not be included in the order letters.

TPL Review for SE0002424-SE0002460, SE0002462, SE0002464-SE0002474, SE0002479-SE0002482, SE0002484, SE0002495-SE0002511, SE0002513-SE0002518, SE0002520-SE0002534, and SE0002541-SE0002546

<b>SE0002545: Dana International (145)</b>	
<b>SE0002546: Taylor Gang Shop</b>	
Package Type	Booklet
Package Quantity	33 papers
Length	107 mm
Width	44 mm
Characterizing Flavor	None
<b>SE0002425: Nine Drags</b> <b>SE0002426: Cris</b> <b>SE0002428: Free Spirits</b> <b>SE0002430: Gaspipes (009)</b> <b>SE0002431: Brennan's</b> <b>SE0002432: Moderne Primitives (011)</b> <b>SE0002433: Enchanted Planet</b> <b>SE0002434: H. Utopia</b> <b>SE0002435: H. Lines Boutique</b> <b>SE0002436: Piece of Mind (017)</b> <b>SE0002437: Volo-Ryot (018)</b> <b>SE0002438: Grassroots (023)</b> <b>SE0002439: Yellowstone Tobacco Co.</b> <b>SE0002440: Gaspipes (025)</b> <b>SE0002441: Munchies Cafe</b> <b>SE0002442: Carlito's Way</b> <b>SE0002443: Exscape Smoke Shop</b> <b>SE0002444: Stogies Smoke Shop</b> <b>SE0002445: Gold Rush (030)</b> <b>SE0002446: Whelan's Smoke Shop</b> <b>SE0002447: Capitol Hemp (032)</b> <b>SE0002448: Tasty Puff LLC (033)</b> <b>SE0002449: Kind Connection III</b> <b>SE0002450: Slightly Stoopid (035)</b> <b>SE0002452: Octopus Garden II</b> <b>SE0002454: Perfect Place</b> <b>SE0002455: Easy's</b> <b>SE0002456: P-n-S</b> <b>SE0002459: Humboldt Fire</b> <b>SE0002460: Aaron's Rock 'n' Roll (049)</b> <b>SE0002464: Adrenalin Rush (053)</b> <b>SE0002466: Voodoo Willy's Smoke Hut</b> <b>SE0002467: H.O.H.</b> <b>SE0002472: Smoker's Corner</b> <b>SE0002473: Utopia</b> <b>SE0002474: Krutch (064)</b> <b>SE0002479: Habits</b>	

TPL Review for SE0002424-SE0002460, SE0002462, SE0002464-SE0002474, SE0002479-SE0002482, SE0002484, SE0002495-SE0002511, SE0002513-SE0002518, SE0002520-SE0002534, and SE0002541-SE0002546

<b>SE0002482: Piece of Mind (076)</b>	
<b>SE0002484: The Magic Bus</b>	
<b>SE0002495: Volo-Ryot (089)</b>	
<b>SE0002496: Mr. Nice Guy</b>	
<b>SE0002497: Casa de los Muertos</b>	
<b>SE0002498: The Levitation Project</b>	
<b>SE0002499: Grassroots (093)</b>	
<b>SE0002500: Kulture (094)</b>	
<b>SE0002502: Dreams</b>	
<b>SE0002503: Pandora's Box</b>	
<b>SE0002504: T-Zone</b>	
<b>SE0002505: Retro-Active</b>	
<b>SE0002507: Gold Rush (103)</b>	
<b>SE0002508: Capitol Hemp (104)</b>	
<b>SE0002513: Tobacco Town</b>	
<b>SE0002518: Ithaca Hemp (114)</b>	
<b>SE0002521: Trendsetters</b>	
<b>SE0002525: Hitman Glass</b>	
<b>SE0002526: KMG Direct</b>	
<b>SE0002527: Black Box Music</b>	
<b>SE0002529: The Grow Show</b>	
<b>SE0002530: Dana International (129)</b>	
<b>SE0002531: Lucky Raven</b>	
<b>SE0002532: Mystik Treasure</b>	
<b>SE0002541: Smokin Glasswork</b>	
<b>SE0002542: Pugs Discount Tobacco</b>	
<b>SE0002543: Unique Dollar Plus</b>	
<b>SE0002544: Headlines</b>	
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	Provisional Same Characteristics
Product Category	Roll-Your-Own Tobacco
Product Sub-Category	Rolling Paper
<b>Recommendation</b>	
Issue Substantially Equivalent (SE) orders.	

TPL Review for SE0002424-SE0002460, SE0002462, SE0002464-SE0002474, SE0002479-SE0002482, SE0002484, SE0002495-SE0002511, SE0002513-SE0002518, SE0002520-SE0002534, and SE0002541-SE0002546

**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:

**SE0002424: Nine Dragons**  
**SE0002427: Cris2**  
**SE0002429: Kulture (008);**  
**SE0002451: Treasure Chest**  
**SE0002453: Wiz Khalifa**  
**SE0002457: Whelan's**  
**SE0002458: Bocomo Bay (047)**  
**SE0002462: Gord's Smoke Shop**  
**SE0002465: Adrenalin Rush (054)**  
**SE0002468: H. Flyer**  
**SE0002469: Holy Smoke**  
**SE0002470: Tasty Puff**  
**SE0002471: Slightly Stoopid (061)**  
**SE0002480: Sky Dancer**  
**SE0002481: Smokin' J's (075)**  
**SE0002501: Kulture (095)**  
**SE0002506: South Union Bar and Grill**  
**SE0002509: Capitol Hemp (105)**  
**SE0002510: Aaron's Rock and Roll (106)**  
**SE0002511: Moderne Primitives (107)**  
**SE0002514: Krutch**  
**SE0002515: Paper Airplanes**  
**SE0002516: Waaves**  
**SE0002517: Ithaca Hemp (113)**  
**SE0002520: Spectrum Labs**  
**SE0002522: Bocomo Bay (118)**  
**SE0002523: Slightly Stoopid (119)**  
**SE0002524: Purple Haze**  
**SE0002528: Slug Magazine**  
**SE0002533: Mr. Eddies Headies**  
**SE0002534: Easy**

TPL Review for SE0002424-SE0002460, SE0002462, SE0002464-SE0002474, SE0002479-SE0002482, SE0002484, SE0002495-SE0002511, SE0002513-SE0002518, SE0002520-SE0002534, and SE0002541-SE0002546

<b>SE0002545: Dana International (145)</b>	
<b>SE0002546: Taylor Gang Shop</b>	
Product Name	Chris Hill (King)
Package Type	Booklet
Package Quantity	33 papers
Length	107 mm
Width	44 mm
Characterizing Flavor	None
<b>SE0002425: Nine Drags</b> <b>SE0002426: Cris</b> <b>SE0002428: Free Spirits</b> <b>SE0002430: Gaspipes (009)</b> <b>SE0002431: Brennan's</b> <b>SE0002432: Moderne Primitives (011)</b> <b>SE0002433: Enchanted Planet</b> <b>SE0002434: H. Utopia</b> <b>SE0002435: H. Lines Boutique</b> <b>SE0002436: Piece of Mind (017)</b> <b>SE0002437: Volo-Ryot (018)</b> <b>SE0002438: Grassroots (023)</b> <b>SE0002439: Yellowstone Tobacco Co.</b> <b>SE0002440: Gaspipes (025)</b> <b>SE0002441: Munchies Cafe</b> <b>SE0002442: Carlito's Way</b> <b>SE0002443: Exscape Smoke Shop</b> <b>SE0002444: Stogies Smoke Shop</b> <b>SE0002445: Gold Rush (030)</b> <b>SE0002446: Whelan's Smoke Shop</b> <b>SE0002447: Capitol Hemp (032)</b> <b>SE0002448: Tasty Puff LLC (033)</b> <b>SE0002449: Kind Connection III</b> <b>SE0002450: Slightly Stoopid (035)</b> <b>SE0002452: Octopus Garden II</b> <b>SE0002454: Perfect Place</b> <b>SE0002455: Easy's</b> <b>SE0002456: P-n-S</b> <b>SE0002459: Humboldt Fire</b> <b>SE0002460: Aaron's Rock 'n' Roll (049)</b> <b>SE0002464: Adrenalin Rush (053)</b> <b>SE0002466: Voodoo Willy's Smoke Hut</b> <b>SE0002467: H.O.H.</b> <b>SE0002472: Smoker's Corner</b> <b>SE0002473: Utopia</b> <b>SE0002474: Krutch (064)</b>	

TPL Review for SE0002424-SE0002460, SE0002462, SE0002464-SE0002474, SE0002479-SE0002482, SE0002484, SE0002495-SE0002511, SE0002513-SE0002518, SE0002520-SE0002534, and SE0002541-SE0002546

<b>SE0002479: Habits</b>	
<b>SE0002482: Piece of Mind</b>	
<b>SE0002484: The Magic Bus</b>	
<b>SE0002495: Volo-Ryot (089)</b>	
<b>SE0002496: Mr. Nice Guy</b>	
<b>SE0002497: Casa de los Muertos</b>	
<b>SE0002498: The Levitation Project</b>	
<b>SE0002499: Grassroots (093)</b>	
<b>SE0002500: Kulture (094)</b>	
<b>SE0002502: Dreams</b>	
<b>SE0002503: Pandora's Box</b>	
<b>SE0002504: T-Zone</b>	
<b>SE0002505: Retro-Active</b>	
<b>SE0002507: Gold Rush (103)</b>	
<b>SE0002508: Capitol Hemp (104)</b>	
<b>SE0002513: Tobacco Town</b>	
<b>SE0002518: Ithaca Hemp (114)</b>	
<b>SE0002519: Rolling Paper Depot</b>	
<b>SE0002521: Trendsetters</b>	
<b>SE0002525: Hitman Glass</b>	
<b>SE0002526: KMG Direct</b>	
<b>SE0002527: Black Box Music</b>	
<b>SE0002529: The Grow Show</b>	
<b>SE0002530: Dana International (129)</b>	
<b>SE0002531: Lucky Raven</b>	
<b>SE0002532: Mystik Treasure</b>	
<b>SE0002541: Smokin Glasswork</b>	
<b>SE0002542: Pugs Discount Tobacco</b>	
<b>SE0002543: Unique Dollar Plus</b>	
<b>SE0002544: Headlines</b>	
	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.



TPL Review for SE0002424-SE0002460, SE0002462, SE0002464-SE0002474, SE0002479-SE0002482, SE0002484, SE0002495-SE0002511, SE0002513-SE0002518, SE0002520-SE0002534, and SE0002541-SE0002546

## 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

FDA received these SE Reports on March 22, 2011. These are provisional tobacco products because the new tobacco products were first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007 but before March 22, 2011, and the SE Reports were submitted to FDA by March 22, 2011. Acknowledgement letters were issued for these reports on the following dates:

- September 14, 2011: SE0002495-SE0002511, SE0002513-SE0002518, SE0002520-SE0002534, SE0002541-SE0002546
- October 7, 2011: SE0002424-SE0002439, SE0002441-SE0002444, SE0002446, SE0002449, SE0002451-SE0002457, SE0002459, SE0002462, SE0002466-SE0002470, SE0002472, SE0002473, SE0002479, SE0002480, SE0002484
- December 1, 2011: SE0002440, SE0002445
- December 5, 2011: SE0002447, SE0002448, SE0002450, SE0002458, SE0002460, SE0002471, SE0002474, SE0002481, SE0002482

Public Health Impact (PHI) reviews were finalized on the following dates:

- August 27, 2012: SE0002425
- September 3, 2012: SE0002424, SE0002426-SE0002455
- September 7, 2012: SE0002456-SE0002460
- September 9, 2012: SE0002462, SE0002464-SE0002474, SE0002479-SE0002482, SE0002484, SE0002495-SE0002511, SE0002513-SE0002518, SE0002520-SE0002525-SE0002534, SE0002541-SE0002546

Based on the reviews, all of the SE Reports were assigned to PHI Tier 3. FDA sent Advice/Information Request letters (A/I letters) for SE0002424-SE0002460, SE0002462, and SE0002464-SE0002474 to the applicant on January 24, 2013. The letters were returned to FDA as undeliverable. Because the mail delivery services did not use tracking, FDA could not determine the reason for unsuccessful mail delivery. To address the issue, FDA sent another A/I letter for SE0002424-SE0002546 using tracking mail service to ensure delivery and tracking of the letter to the applicant on June 23, 2014. The second letter was also returned to FDA as undeliverable; it was undeliverable because the receiver name did not match the company name that the letter was addressed to.

FDA attempted to contact the applicant via telephone on December 3, 10, and 20, 2012 to discuss the SE Reports. Voice messages were left by FDA, with no return telephone call received by FDA. On June 5, 2013, FDA attempted to contact the applicant via email. FDA did not receive a

TPL Review for SE0002424-SE0002460, SE0002462, SE0002464-SE0002474, SE0002479-SE0002482, SE0002484, SE0002495-SE0002511, SE0002513-SE0002518, SE0002520-SE0002534, and SE0002541-SE0002546

message that the email was undeliverable, but no communication was received by FDA in response to the email. To date, the applicant has not returned any of FDA's telephone calls or email. FDA has not received any amendments in response to any issued letters nor received any formal requests to withdraw the SE Reports. Based on the lack of response to multiple A/I letters, phone calls, and email, the applicant is considered a non-responder, and the SE Reports are being handled accordingly.<sup>2</sup> Although SE Reports in PHI Tier 3 have not undergone scientific review yet, all of the SE Reports subject of this TPL review entered scientific review based on the applicant's non-responder status. Following the SE review process, FDA sent a Notification letter on September 5, 2014, informing the applicant that FDA expected to begin scientific review on October 20, 2014. The letter was returned to FDA as undeliverable.

Furthermore, because these SE Reports lack sufficient detail to make a final determination of substantial equivalence, FDA sent the applicant a Preliminary Finding letter on October 31, 2014. This letter indicated that the applicant should respond to the letter by November 30, 2014. On November 28, 2014, FDA received an incomplete amendment (SE0010765) in response to the Preliminary Finding letter. On February 23, 2015, FDA sent the applicant a Preliminary Finding letter with different deficiencies than the November 2014 Preliminary Finding letter, indicating that the applicant should respond to the letter by March 25, 2015. This Preliminary Finding letter included some of the same deficiencies as the October 2014 Preliminary Finding letter but also included new deficiencies determined during substantive scientific review. On March 25, 2015, FDA received an amendment (SE0011045) containing response to the Preliminary Finding letter. The amendment suggested that that SE Reports should be reclassified as Same Characteristics SE Reports as identified in the guidance document titled "Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions" that FDA issued on March 4, 2015. Because the amendment was not clear about the classification of the SE Reports, FDA held a teleconference with the applicant on March 31, 2015, during which the applicant clarified that FDA should consider these reports as Same Characteristics SE Reports. On May 4, 2015, FDA held a teleconference with the applicant to request written documentation confirming that the reports are Same Characteristics SE Reports. In addition, FDA requested additional information to uniquely identify the new and predicate tobacco products. In response, the applicant submitted an amendment (SE0011753) on May 11, 2015. On May 15, 2015, FDA sent the applicant an email requesting information regarding the Environmental Assessment. In response, FDA received an amendment on May 29, 2015 (SE0011901).

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<sup>2</sup> See the September 5, 2014, memorandum by Cristi Stark describing OS's criteria for defining a non-responder and OS's process for handing provisional SE Reports from applicants who are non-responders.

### **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 February 20, 2015, and September 25, 2015. The final review concludes that each SE Report includes all of the information recommended in the 2015 SE FAQ guidance document for a Same Characteristics SE Report:

1. The SE Reports are identified as “Same Characteristics SE Reports.”
2. The new and predicate tobacco products are uniquely identified.
3. There is a statement indicating that the applicant intends to market the new and predicate tobacco products.
4. An Environmental Assessment was provided.
5. 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.
6. There is a statement indicating that the applicant will comply with any applicable standards under section 907 of the FD&C Act.
7. The certification statement included in the guidance document is provided, 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 January 5, 2015, conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products are eligible predicate tobacco products.<sup>3</sup>

## **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. Therefore, scientific review is unnecessary.

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<sup>3</sup> Addendum reviews were completed in September 21 and 23, 2015, to correct identification of the predicate and new tobacco products; the conclusions in these addendum reviews did not differ from that in the original January 5, 2015, reviews.

TPL Review for SE0002424-SE0002460, SE0002462, SE0002464-SE0002474, SE0002479-SE0002482, SE0002484, SE0002495-SE0002511, SE0002513-SE0002518, SE0002520-SE0002534, and SE0002541-SE0002546

## **5. ENVIRONMENTAL DECISION**

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on August 3, 2015. The FONSI was supported by an environmental assessment prepared by FDA on August 3, 2015.

## **6. CONCLUSION AND RECOMMENDATION**

The product characteristics of the new and corresponding tobacco predicate products are the same. In all SE Reports, the product names differ between the new and corresponding predicate tobacco products. The SE Reports includes all of the information recommended in the 2015 SE FAQ guidance document for a Same Characteristics SE Report.

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).

The new tobacco products are currently in compliance with the FD&C Act. 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 SE0002424-SE0002460, SE0002462, SE0002464-SE0002472, SE0002474, SE0002479-SE0002482, SE0002484, SE0002495-SE0002511, SE0002513-SE0002518, SE0002520-SE0002534, and SE0002541-SE0002546, as identified on the cover page of this review except as noted in footnote 1.