

**Technical Project Lead (TPL) Review: SE0002188**

<b>SE0002188: Old Gold Blue 100s</b>	
<b>Package Type</b>	Soft Pack
<b>Package Quantity</b>	20 cigarettes
<b>Length</b>	99 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	68%
<b>Characterizing Flavor</b>	None
<b>Attributes of SE Report</b>	
<b>Applicant</b>	R.J. Reynolds Tobacco Company
<b>Report Type</b>	Provisional
<b>Product Category</b>	Cigarette
<b>Product Sub-Category</b>	Combusted Filtered
<b>Recommendation</b>	
Issue Substantially Equivalent (SE) order.	

**Technical Project Lead (TPL):**

Digitally signed by Charles Feng -S  
Date: 2019.12.06 11:16:59 -05'00'

Charles Feng, Ph.D.  
Chemistry Branch Chief  
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)

Digitally signed by Matthew R. Holman -S  
Date: 2019.12.06 11:42:48 -05'00'

Matthew R. Holman, Ph.D.  
Director  
Office of Science

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## 1. BACKGROUND

### 1.1. PREDICATE TOBACCO PRODUCT

The applicant submitted the following predicate tobacco product:

SE0002188: Old Gold Blue 100s	
Product Name	Old Gold Ultra Lights 100s
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.9 mm
Ventilation	64%
Characterizing Flavor	None

The predicate tobacco product is a combusted, filtered cigarette manufactured by the applicant.

### 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

FDA received the SE Report for SE0002188 on March 22, 2011 from Lorillard Tobacco Company.<sup>1</sup> FDA issued an Acknowledgement letter on August 23, 2011. On October 28, 2011, FDA received an unsolicited amendment (SE0003824) from the applicant which provided an environmental assessment. FDA issued an Advice/Information Request (A/I) letter to the applicant on January 4, 2013. On February 1, 2013, FDA received the applicant's response to the A/I letter (SE0006996). On February 10, 2014, FDA received a solicited amendment (SE0010173) from the applicant in response to a request for length and package quantity for the new and predicate products. FDA issued a Notification letter on March 11, 2019 stating that FDA would begin scientific review of the SE Report within 180 days from issuance of the letter. On September 4, 2019, FDA received amendment (SE0015425) from the applicant containing a revised SE Report.

Product Name	SE Report	Amendments
Old Gold Blue 100s	SE0002188	SE0003824 SE0006996 SE0010173 SE0015425

### 1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for this SE Report.

<sup>1</sup> FDA acknowledged the transfer of ownership from Lorillard Tobacco Company to R.J. Reynolds Tobacco Company on October 1, 2015.

## **2. REGULATORY REVIEW**

Regulatory reviews were completed by Rosanna Beltre on January 4, 2013 and Angela Brown on March 11, 2014. The final review concludes that the SE Report is administratively complete.

## **3. COMPLIANCE REVIEW**

The Office of Compliance and Enforcement (OCE) completed a review to determine whether the applicant established that the predicate tobacco product is a grandfathered product (i.e., was commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The OCE review dated October 9, 2019, concludes that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco product is grandfathered and, therefore, is an eligible predicate tobacco product.

## **4. SCIENTIFIC REVIEW**

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

### **4.1. CHEMISTRY**

A chemistry review was completed by Abdur-rafay Shareef on October 29, 2019.

The chemistry review concludes that the new tobacco product has different characteristics related to product chemistry compared to the predicate tobacco product, but the differences do not cause the new tobacco product to raise different questions of public health. The review identified the following difference:

- Replacement of non-FSC cigarette paper with FSC cigarette paper

A change from non-FSC paper to FSC paper may lead to higher mainstream yields of HPHCs. The applicant provided TNCO yields under both ISO and CI smoking regimens. CO yield under the CI regimen was 11% higher in the new tobacco product, which was analytically non-equivalent as compared to the predicate tobacco product. This higher CO yield was deferred to toxicology for further evaluation. All other TNCO yields were analytically equivalent, and therefore, the difference does not cause the new tobacco product to raise different questions of public health from a chemistry perspective.

### **4.2. ENGINEERING**

An engineering review was completed by Drew Katherine on October 18, 2019.

The engineering review concludes that the new tobacco product has different characteristics related to product engineering compared to the predicate tobacco product, but the differences do not cause the new tobacco product to raise different questions of public health. The review identified the following difference:

- Replacement of non-FSC cigarette paper with FSC cigarette paper

From an engineering perspective, the only significant difference is a change from a non-FSC to an FSC cigarette paper. The benefit of using FSC paper in cigarettes to reduce household fires is anticipated to outweigh any potential increased health risks from the small increases in HPHC exposures that may occur from the use of the FSC paper, if the only change in a new combusted tobacco product is the change to FSC paper. Therefore, the difference does not cause the new tobacco product to raise different questions of public health from an engineering perspective.

#### 4.3. TOXICOLOGY

A toxicology review was completed by Chad Brocker on October 31, 2019.

The toxicology review concludes that the new tobacco product has different characteristics related to product toxicology compared to the predicate tobacco product, but the differences do not cause the new tobacco product to raise different questions of public health. The review identified the following differences:

- Replacement of non-FSC cigarette paper with FSC cigarette paper
- Addition of (b) (4) (b) (4) )
- Replacement of (b) (4) with (b) (4)
- Replacement of (b) (4)
- Increase of CO yield under CI regimen

In addition to a change from non-FSC cigarette paper to FSC paper, the toxicology review identified several ingredient changes including (b) (4). However, these ingredient changes are associated with the non-FSC to FSC cigarette paper change. Furthermore, exposures at the levels reported for these ingredients are unlikely to cause toxicological concerns. An increase (11%) in CO yield was also observed. However, from an overall public health perspective, Office of Science's current thinking is that if the only change in a new combusted tobacco product is the change to FSC paper, the new tobacco product incorporating FSC paper does not raise different questions of public health compared to the corresponding predicate products incorporating non-FSC paper. Therefore, the information provided by the applicant indicates ingredient changes in the new tobacco product do not raise different questions of public health.

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

#### 5. ENVIRONMENTAL DECISION

Under 21 CFR 25.35(a), issuance of an SE order under section 910(a) of the FD&C Act for this provisional SE Report SE0002188 is categorically excluded and, therefore, normally does not require the preparation of an environmental assessment (EA) or an environmental impact statement. FDA

has considered whether there are extraordinary circumstances that would require the preparation of an EA and has determined that none exist.

## 6. CONCLUSION AND RECOMMENDATION

The following are the key differences in characteristics between the new and predicate tobacco product:

- Replacement of non-FSC cigarette paper with FSC cigarette paper and associated changes in ingredients and CO yield
  - Addition of (b) (4)
  - Replacement of (b) (4) with (b) (4)
  - Replacement of (b) (4)
  - Increase of CO yield under CI regimen

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco product to raise different questions of public health. The only significant difference between the new and predicate tobacco products is a change from non-FSC paper to FSC paper. There are some other changes in ingredients associated with the cigarette paper change. However, the toxicology review concluded that these ingredient changes at the reported levels are unlikely to cause toxicological concerns. The applicant reported an analytically non-equivalent increase (11%) in CO under the CI smoking regimen. However, Office of Science has determined, given the information currently available on the changes that have been observed in HPHC yields as a result of switching from non-FSC to FSC cigarette paper, the benefit of using FSC paper in cigarettes to reduce household fires is anticipated to outweigh any potential increased health risks from the small increases in HPHC exposures that may occur from the use of FSC cigarette paper. Therefore, the differences in characteristics between the new and predicate tobacco product do not cause the new tobacco product to raise different questions of public health.

The predicate tobacco product meets statutory requirements because it was determined that it is a grandfathered product (i.e., was commercially marketed in the United States other than exclusively in test markets as of February 15, 2007).

Because the proposed action is issuing an SE order for this provisional SE Report, it is a class of action that is categorically excluded under 21 CFR 25.35(a). FDA has considered whether there are extraordinary circumstances that would require the preparation of an environmental assessment and has determined that none exist. Therefore, the proposed action does not require preparation of an environmental assessment or an environmental impact statement.

An SE order letter should be issued for the new tobacco product in SE0002188, as identified on the cover page of this review.