

### Addendum

The TPL review signed by me on June 26, 2015, contains an omission. Within the TPL review, an SE Report is missing. The June 26, 2015 TPL review contains the following SE Reports:

SE0011287, SE0011289, SE0011291, SE0011296, SE0011298, SE0011305, SE0011308, SE0011309, SE0011310, SE0011312, SE0011321, SE0011324, SE0011326, SE0011327, SE0011328, SE0011333, SE0011338, SE0011347, SE0011354, SE0011357, SE0011362, SE0011363, SE0011373, SE0011379, SE0011381, SE0011383, SE0011384, SE0011385, SE0011386, SE0011393, SE0011397, SE0011398, SE0011399, SE0011400, SE0011401, SE0011402, SE0011408, SE0011409, SE0011412, SE0011413, SE0011416, SE0011417, SE0011419, SE0011421, SE0011423, SE0011468, SE0011469, SE0011471, SE0011473, SE0011474, SE0011469, SE0011471, SE0011473, SE0011474, SE0011476, SE0011478, SE0011480, SE0011487, SE0011494, SE0011497, SE0011498, SE0011499, SE0011501, SE0011509, SE0011512, SE0011514, SE0011515, SE0011516, SE0011521, SE0011525, SE0011534, SE0011541, SE0011544, SE0011549, SE0011550, SE0011566, SE0011568, SE0011571, SE0011572, SE0011573, SE0011576, SE0011580, SE0011584, SE0011585, SE0011586, SE0011587, SE0011588, SE0011589, SE0011596, SE0011597, SE0011600, SE0011601, SE0011603, SE0011604, SE0011605, SE0011607, SE0011608, SE0011609, SE0011611, SE0011656, SE0011657, SE0011659, SE0011661, SE0011662

This addendum serves to correct the omission so that the TPL review is accurate. The TPL review should have included the following SE Report:

**SE0011415: Adam Marsh King**

Package Type: Booklet  
Package Quantity: 33 papers  
Length: 107 mm  
Width: 44 mm  
Characterizing Flavor: None

This SE Report was inadvertently omitted from the TPL review. For SE0011415, the basis for finding the new tobacco product substantially equivalent is the same as basis listed in the June 26, 2015, TPL review: the product names differ between the new and predicate tobacco products, but the characteristics of the new and predicate tobacco products are the same (i.e., identical characteristics). The SE Report includes all of the information needed by FDA to make a substantial equivalence determination: the predicate tobacco product meets statutory requirements because it is a grandfathered product (i.e., was commercially marketed in the United States as of February 15, 2007), and the new tobacco product is currently in compliance with the FD&C Act.

For SE0011415, the predicate tobacco product is:

Chris Hill King  
Package Type: Booklet  
Package Quantity: 33 papers  
Length: 107 mm  
Width: 44 mm  
Characterizing Flavor: None

A Substantially Equivalent order letter was issued for this SE Report on June 29, 2015, reflective of the fact that it should have been included in the TPL review.

**Technical Project Lead (TPL):**



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