

## Review

**To:** File SE0014130 Digitally signed by Ryan Nguy -S  
Date: 2018.08.15 09:04:20  
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**From:** Ryan Nguy, Regulatory Health Project Manager, Branch II  
**Through:** Anne M. Radway, M.S., Chief, Regulatory Project Management Branch II  
Digitally signed by Anne M. Radway -S  
Date: 2018.08.15 09:44:46 -04'00'  
**Company:** U.S. Smokeless Tobacco Company LLC (USSTC)  
**Subject:** Correction SE Order letter for SE0014130

**Table 1: Submission Tracking Number (STN)/Product Subject of This Memo**

<u>STN</u>	<u>TOBACCO PRODUCT NAME</u>
SE0014130	Rooster Long Cut Mint

### BACKGROUND

On June 2, 2017, FDA received three Substantial Equivalence (SE) Reports (SE0014130 – SE0014132) from Altria Client Services LLC (ALCS) on behalf of USSTC. FDA issued Acknowledgement letters on June 21, 2017. FDA issued Advice/Information Request letters (A/I letters) for all STNs on August 25, 2017. On October 24, 2017, FDA received responses (SE0014389) to the A/I letter. FDA issued a Preliminary Finding (PFind) letter on January 22, 2018. On February 20, 2018, FDA received responses (SE0014540) to the PFind letter. SE Order letters were issued on May 24, 2018.

### DISCUSSION

On May 30, 2018, ALCS held a teleconference with FDA to inform FDA of an error in the SE Order letter for SE0014130 regarding the package type of the new tobacco product. ALCS indicated that FDA’s SE Order letter identified the package type as “Plastic Can and Lid”, however, the SE Order letter should indicate “Plastic Can and Metal Lid.” Upon further review of the SE Report, amendments, and the final TPL Review, FDA confirmed that the package type should have stated “Plastic Can and Metal Lid” and incorrectly indicated “Plastic Can and Lid” on the SE Order letter.

### CONCLUSION AND RECOMMENDATION

FDA will issue a Correction SE Order letter for SE0014130, with the package type as Plastic Can and Metal Lid. The table below shows the modified information for the Correction SE Order letter.

STN	Tobacco Product Name	Package Type (Original SE Order)	Package Type (Correction SE Order)
SE0014130	Rooster Long Cut Mint	Plastic Can and Lid	Plastic Can and Metal Lid