

**From:** Houck, Christina M  
**Sent:** Monday, February 13, 2017 2:07 PM  
**To:** Kim Sullivan (sullivan@smarthealth.com)  
**Subject:** STN 125579/0 Label  
**Importance:** High

Dear Kim,

We are reviewing your BLA for STN 125579/0 for Rubber Panel T.R.U.E. TEST (Rubber Panel Thin- Layer Rapid Use Epicutaneous Patch Test) for “use as an aid in the diagnosis of allergic contact dermatitis in persons six years of age and older whose history suggests sensitivity to one or more of the five substances included on the Rubber Panel T.R.U.E. TEST.” We have completed our review of the attached draft package insert submitted on November 16, 2016 and have no additional edits. We accept the package insert as final draft labeling for the BLA.

Kind Regards,  
Christina

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