

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

Christina Houck
Regulatory Project Manager
Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Vaccines Research and Review
10903 New Hampshire Avenue
White Oak Bldg. 71
Silver Spring, MD 20993
Tel: [301-796-2640](tel:301-796-2640)
Fax: [301-827-3532](tel:301-827-3532)
Email: christina.houck@fda.hhs.gov

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.