

From: [Valenti, Elizabeth](#)
To: [Kim M. Sullivan \(SULLIVAN@smarthealth.com\)](#)
Cc: [Houck, Christina M](#); [Valenti, Elizabeth](#)
Subject: Information Request, STN 125579/0
Date: Friday, June 03, 2016 2:51:00 PM

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.” After further review we have the following information request:

1. Please identify and qualify a room for storage of your Rubber Panel T.R.U.E. TEST product prior to manufacturing lots for distribution. Please qualify your storage room to demonstrate reliable control and operation at the specified temperature of 20-25°C and (b) (4) relative humidity under both empty and loaded conditions. In addition, please utilize a monitoring system to provide assurance that the room meets the required storage conditions for the product. Please confirm that you will institute these requirements prior to manufacturing of your next lot of Rubber Panel T.R.U.E. TEST for distribution, and will have results of qualification studies and routine monitoring data available for review during your next surveillance inspection.
2. Please note that shipping conditions of the product need validation and/or monitoring to assure product remains in the specified and controlled temperature range during shipment. Please confirm that you will institute these requirements prior to distribution of your next lot of Rubber Panel T.R.U.E. TEST. Please have results of shipping validation studies and shipping monitoring available for review during your next surveillance inspection.
3. We recommend that you revise your proposed Date of Manufacture (DOM) to a specific process step such as the date of initiation of final product assembly. In your response to this Information Request, please state the DOM you will use for the Rubber Panel T.R.U.E. TEST. In addition, please confirm that you will revise your batch records and procedures to include your revised DOM prior to manufacturing your next lot of final product.

Thank you, Betsy

Elizabeth J. Valenti, MPH, RAC (U.S.), REHS/RS
CDR, USPHS
Project Manager
Food and Drug Administration
Center for Biologics Evaluation and Research
Office of the Director, Review Management
Business Operations Staff
10903 New Hampshire Ave.
Building 71, Room 7307A
Silver Spring, MD 20993-0002

elizabeth.valenti@fda.hhs.gov

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