

## Houck, Christina M

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**From:** Houck, Christina M  
**Sent:** Wednesday, September 30, 2015 1:56 PM  
**To:** Kim Sullivan (sullivan@smarthealth.com)  
**Subject:** IR for STN 125579 Rubber Panel

**Importance:** High

Dear Kim,

We are reviewing your BLA for STN 125579 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:

Product:

Please provide the following information regarding quality systems requirements for the device component of your product:

1. Please provide documents and procedures that control the design process of the device component of Rubber Panel T.R.U.E. TEST. These procedures should address the following elements:
  - a. Procedures that address ensuring design requirements are appropriate in meeting the intended use of the device component;
  - b. Procedures that define the evaluation of the product’s acceptance criteria for conformance to design requirements of the device component;
  - c. Procedures that address the review, verification, and validation of the device component design;
  - d. Procedures addressing the documentation, verification, review, and approval of design changes prior to implementation; and
  - e. Design history file that contains or references records demonstrating development of the device component.

Please note if your product was developed outside of a formal design control process the process can be documented retrospectively. Any existing data or validation efforts may be leveraged to address particular design control elements.

The design history file for your combination product should address all design issues relating to the combined use of the constituent parts. The design history file does not need to document design and development planning for your legacy product or the Rubber Panel T.R.U.E. TEST. It is appropriate to leverage existing data in developing your design history file. For example, existing specifications may become part of the required design output documentation. Similarly, testing performed prior to distribution of the combination product may be included as documentation of design verification and validation.

You are responsible for assembling available information and assessing what, if any, additional information and evidence may be needed, such as additional testing or documentation of design control activities, to address all aspects of design control that are needed to support the manufacture of the Rubber Panel T.R.U.E. TEST, ensure its safety and effectiveness, and support any future changes to that product. However, you do not need to prepare a development plan or conduct design review meetings for your Rubber Panel T.R.U.E. TEST because the development stages that these activities would support have already occurred.

2. Please describe your procedures and other documentation utilized for evaluating, approving, and controlling suppliers as per 21 CFR Part 820.50 for the device component.
3. Please describe your procedures for implementation of corrective and preventive actions as per 21 CFR Part 820.100 for device component.

If any of the preceding items have not been performed by your organization, please provide your gap analysis in your response showing the topics that need to be addressed. Please also include in your response a plan and timeline for completion of each of the above requirements.

#### Chemistry Manufacturing and Controls

4. Please provide legible copies of executed batch records for the manufacture and assembly of Rubber Panel T.R.U.E. TEST.

#### Clinical:

5. As previously requested in comment #1 from our January 12, 2015 Complete Response Letter to you and to ensure a complete review of your BLA submission, please provide the following information for your clinical study, entitled "Mekos 07 29P1/2/3 401: Clinical Evaluation of T.R.U.E. TEST® Panel 1.1, 2.1 and 3.1 in Children and Adolescents:"
  - a. Debarment Certification (item 1.b.xvii)
  - b. Financial Certification and Disclosure (item 1.b.xvii)
  - c. FDA Form 3454 (item 1.b.xix)

#### Regulatory:

6. Please submit to your BLA a statement to cross-reference your currently licensed product, STN 103738, T.R.U.E. TEST (Thin-Layer Rapid Use Epicutaneous Patch Test). Please include the STN(s) and approval date(s) for the relevant allergens. This statement will authorize us to include the adult data for carba mix, black rubber mix, mercapto mix, thiuram mix, and mercaptobenzothiazole in evaluating Rubber Panel T.R.U.E. TEST and labeling for BLA 125579/0.

In order to allow adequate time to conduct our review during this review cycle, please submit a response to the above information requests by Friday, October 30, 2015.

Regards,

Christina

Christina Houck  
Regulatory Project Manager  
Food and Drug Administration

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