



**MEMORANDUM**

**Date:** 02 February, 2016

**From:** Karen Campbell

Division of Biological Standards and Quality Control (DBSQC)

Office of Compliance and Biologics Quality (OCBQ)

Center for Biologics Evaluation and Research (CBER)

Food and Drug Administration (FDA)

**To:** **Biologics License Application Submission Tracking Number # 125579/0**

**Subject:** **Review of Lot Release Protocol Templates for Drug Substance and Drug Product of Biologics License Application for rubber Panel Thin-Layer Rapid Use Epicutaneous Patch Test**

**Through:** William M. McCormick, Ph.D., Director, DBSQC/OCBQ/CBER/FDA

**Cc:** Christina Houck, Lead RPM, DVRPA/ OVR

Elizabeth Valenti, Chair, BLA Review Committee, DBPAP/OVR

**Applicant:** SmartPractice Denmark ApS

**Product:** Trade Name – Rubber Panel T.R.U.E. Test

## **1 General Information**

### **1.1 CMC Review Identifiers and Dates**

#### **1.1.1 Biologics License Application (BLA) Submission Tracking Number (STN) #: 125579**

#### **1.1.2 Submission received by CBER: January 9, 2006**

#### **1.1.3 Review completed: February 1, 2016**

#### **1.1.4 Material Reviewed**

##### **Original BLA:**

The following general module sections of the BLA were reviewed: M3 CMC, Quality

#### **1.1.5 Related Master File, INDs and BLAs:** The submission was originally received as a supplement to STN 103738 Allegen Patch Test Kit

### **2 Executive Summary:** The lot release protocol template submitted in amendment 125579/0.13 on 30-Oct-2015 is acceptable for use.

## **3 Review**

### **3.1 Documents Reviewed**

1. Lot Release Protocol Template submitted in amendment 125579/0.8 on 14-Aug-2014
2. Lot Release Protocol Template submitted in amendment 125579/0.13 on 30-Oct-2015

### **3.2 Review**

The lot release protocol template submitted in amendment 125579/0.8 on 14-Aug-2015 was reviewed by members of DBSQC and PRB (Product Release Branch). The following comments were sent to SmartPractice on 14-Oct-2015

Throughout document:

1. Please correct pagination throughout document.  
Example: Page 1 of 1 should be Page 1 of 10.
2. Please correct STN to 125579

3. Please correct Licensed Name of Product to Rubber Panel Thin-Layer Rapid Use Epicutaneous Patch Test

Page 1

4. Please remove Virus Strain, Labeled Strength, and Stabilizer.

Page 4

5. Please express the Results for the Negative control patch in terms of less than the numerical detection limit that was evaluated, e.g. (b) (4) instead of Passed test.

Page 10

6. Please remove Page 10. It is not needed as Page One has the standard “All tests passed” statement as required.

The revised LRP template was submitted in amendment 125579/0.13 on 30-Oct-2015  
All comments were adequately addressed.

### **3.3 Conclusions**

The lot release protocol template submitted in amendment 125579/0.13 on 30-Oct-2015 is acceptable for use.