



Food and Drug Administration
Center for Biologics Evaluation and Research
10903 New Hampshire Ave
Building 71, G112
Silver Spring, MD 20993-0002

To: Administrative File: STN 125579/0

From: Richard Heath Coats, CMC Facility Reviewer, CBER/OCBQ/DMPQ/BI

Through: Carolyn Renshaw, Branch Chief, CBER/OCBQ/DMPQ/BI

CC: Elizabeth Valenti, Chairperson, CBER/OVRR/DVRPA/CMC1
Christina Houck, RPM, CBER/OVRR/DVRPA/CMC1

Subject: Addendum to Primary Review Memo for BLA for Thin-Layer Rapid Use
Epicutaneous (TRUE) Patch Test Rubber Panel – Review of Amendment
25

Product Rubber Panel Thin-Layer Rapid Use Epicutaneous Patch Test

Indication: Patch test for the diagnosis of contact dermatitis

Applicant: SmartPractice Denmark ApS US License 1888
Herredsvejen 2
3400 Hillerod Denmark
Registration Number 3003216248

Recommendation: Approval

Due Date: March 3, 2017

Summary

SmartPractice has submitted an application to market a new panel containing five rubber related allergen patches (Carba Mix, Black Rubber Mix, Mercaptobenzothiazole, Mercapto Mix, and Thiuram Mix) plus a negative control. All of these rubber related patches are currently on the approved T.R.U.E TEST panel 2.1, and the identical formulation will be used on this new panel. The firm states that no changes will be made to the existing approved panels.

This submission was originally received as a paper submission as a prior approval supplement to the original TRUE Test BLA STN 103738 on January 5, 2006

(103738/5031). The submission was changed to a BLA STN 125579/0 and a Complete Response Letter was issued on January 12, 2015. A resubmission acknowledgement letter was sent to firm on September 21, 2015 that indicated a goal date of February 26, 2016. The Product Office indicated to the review committee that the goal date of February 26, 2016 would not be met. A new goal date of March 3, 2017 has been established and is listed as the due date on Page 1 of this memorandum.

Amendment 25 was submitted on November 15, 2016 by the firm in response to a June 3, 2016 information request sent by the Product Office.

The material in this amendment of DMPQ concern is a requalification report for the firm's storage room of manufactured lots prior to distribution. This addendum review documents the review of this requalification report.

OQ/PQ.R.U.042.01 Revalidation Report Stability Room 25°C, Room (b) (4)

Stability Room (b) (4) is utilized by the firm for storage of stability samples and also storage of final product.

This report summarizes the requalification of stability room (b) (4) at the setpoints of 25°C and (b) (4) RH. Tests performed include a distribution temperature mapping of the room for (b) (4) and power failure tests measuring temperature and humidity decay of the room. Documentation is also provided that demonstrates the sensors measuring temperature and humidity were in calibration at the beginning and conclusion of the qualification.

The data provided shows an acceptable outcome for the specifications in the qualification. Humidity measurements were within the specified range of (b) (4) RH, and temperature measurements were within the specified range of 23 – (b) (4) °C. The summary report indicates no deviations were encountered in execution of this requalification.

The temperature range specified by the firm of 23 – (b) (4) °C is inadequate for this storage room based on the labeled product storage temperature of 25°C. The firm was contacted and instructed to adjust the temperature range for the room so that the maximum allowable temperature would not be greater than 25°C. This communication was sent to the firm by e-mail and uploaded to the EDR (Comment/Advice) by the Product Office on February 17, 2017. DMPQ indicated to the Product Office that a subsequent requalification of this room once the temperature range was adjusted would not need to be submitted by the firm. (b) (5), (b) (7)(E)