



Food and Drug Administration
CBER/OCBQ/DBSQC

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Subject: Test Results for SmartPractice Denmark APS, Thin-Layer Rapid Use
Epicutaneous (T.R.U.E.) Patch Test Rubber Panel, STN: 125579/0,
Lots 96452, 96700.

Allergen patch components:

1) Thiuram Mix by (b) (4)

2) Carba Mix by (b) (4)

To: File STN 125579/0 SmartPractice Denmark ApS US License 1888

Through: Lokesh Bhattacharyya, Ph.D. Lab Chief LACBRP, DBSQC

William McCormick, Ph.D. Director DBSQC

Summary of Testing:

Test results by CBER/DBSQC and SmartPractice Denmark APS indicate compliance with proposed drug product specifications.

SmartPractice submitted samples in support of this application in response to an Information Request by CBER on October 14, 2015. SmartPractice proposed submitting two lots that had been recently manufactured in blank foil and indicated that a third lot, not yet manufactured, would be later submitted with an intention for commercial distribution. Samples of two finished Rubber Panels, Lots 96452 and 96700, were received by CBER/DBSQC in November, 2015 along with test results obtained by SmartPractice in the form of draft rubber panel protocols.

As decided in discussions with the review committee, two of the six allergen patch components of this Panel would be selected for testing by DBSQC. Thiuram Mix and Carba Mix were selected by the DBSQC reviewer as representing two different analytical methodologies to be replicated.

Thiuram Mix

Thiuram Mix (Rubber Panel - Patch 6) was determined by (b) (4) using SmartPractice's procedure 07368-04. Thiuram substances are (b) (4)

[REDACTED]

Table 1: Thiuram Mix Test Results

<u>Lot Number</u>	<u>CBER</u>		<u>SmartPractice</u>
	<u>mg/cm²</u>	<u>Test Date</u>	<u>mg/cm²</u>
96452	0.027	01/14/2016	0.025
96700	0.028	01/14/2016	0.027

Specifications for Thiuram Mix are (b) (4) of the labeled amount of 0.027 mg/cm² ((b) (4)). Results obtained by both CBER and SmartPractice meet this specification.

Carba Mix

Carba Mix (Rubber Panel – Patch 2) was determined by (b) (4) as described in SmartPractice procedure 07397-02. Carba mix is (b) (4)

[REDACTED]

Table 2: Carba Mix Test Results

<u>Lot Number</u>	<u>CBER</u>		<u>SmartPractice</u>
	<u>mg/cm²</u>	<u>Test Date</u>	<u>mg/cm²</u>
96452	0.22	01/07/2016	0.23
96700	0.23	01/07/2016	0.23

Specifications for Carba Mix are (b) (4) of the labeled amount of 0.25 mg/cm² ((b) (4)). Both CBER and SmartPractice results meet this specification.
