

From: [Valenti, Elizabeth](#)
To: [Kim M. Sullivan \(SULLIVAN@smarthealth.com\)](mailto:Kim.M.Sullivan@smarthealth.com)
Cc: [Houck, Christina M](#); [Valenti, Elizabeth](#)
Subject: Re: STN 125579 IR and Request for Samples
Date: Thursday, November 12, 2015 2:45:52 PM
Attachments: [image001.png](#)

Dear Kim,

I have separated out your email response to Christina on October 21, 2015 in order to keep the response for each file separate for our documentation. Regarding your response #3 below in regard to samples for testing for Rubber Panel T.R.U.E. TEST, STN 125579/0. This portion of your email is in response to our October 14, 2015 email IR with comments for the Lot Release Protocol and a request for samples for testing.

Your plan is acceptable. We received your samples from two lots for testing.

Thank you, Betsy

Elizabeth J. Valenti, MPH, RAC (U.S.), REHS/RS
CDR, USPHS
Regulatory Project Manager
Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Vaccine Research and Review
Division of Vaccine Research and Review
10903 New Hampshire Ave.
Building 71, Room 3210
Silver Spring, MD 20993-0002
(301) 796-2640
Main Fax # (301) 595-1124
eFax (301) 402-0004
elizabeth.valenti@fda.hhs.gov

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From: Kim Sullivan [<mailto:sullivan@smarthealth.com>]
Sent: Wednesday, October 21, 2015 5:42 PM
To: Houck, Christina M
Cc: Michael Nielsen
Subject: Re: STN 125579 IR and Request for Samples

Hello Christina,

...

I wanted to give you an update on our responses to the recent IRs:

Subject: STN 125579 IR and Request for Samples

Importance: High

Dear Kim,

We are reviewing your submission for STN 125579 and have the following IR regarding your Lot Release Protocol:

Throughout the Lot Release Protocol document:

1. Please correct pagination throughout document.
Example: Page 1 of 1 should be Page 1 of 10.

2. Please correct the 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.

Please note that the review of this BLA is on-going, further changes may be requested as a result of the review.

REQUEST FOR SAMPLES

-

Please send 10 samples from each of at least 3 lots, intended for release, to the sample custodian at the address below, by November 6, 2015. If the samples are sent before we have approved the lot release protocol template, please send them with the attached concurrent testing letter.

Food and Drug Administration
Center for Biologics Evaluation and Research
Sample Custodian
10903 New Hampshire Avenue
WO75-G707

Silver Spring, MD 20993-0002

Please let me know if you have any questions.

Thank you,

Christina

Christina Houck

Regulatory Project Manager

Food and Drug Administration

Center for Biologics Evaluation and Research

Office of Vaccines Research and Review

10903 New Hampshire Avenue

White Oak Bldg. 71

Silver Spring, MD 20993

Tel: [301-796-2640](tel:301-796-2640)

Fax: [301-827-3532](tel:301-827-3532)

Email: christina.houck@fda.hhs.gov

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