

From: Houck, Christina M
Sent: Wednesday, October 14, 2015 3:01 PM
To: Kim Sullivan (sullivan@smarthealth.com)
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

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.