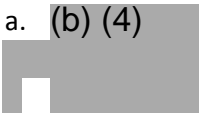



From: Houck, Christina M
Sent: Friday, February 05, 2016 12:48 PM
To: KSmyth@paxvax.com
Cc: Hoffman, Kelsy
Subject: STN 125597 Information Request

Dear Mr. Smyth,

We have the following requests for drug product and buffer samples for in-support testing for STN 125597/0:

1. Please provide two sachets per lot of the following lots of buffer:
 - a. (b) (4)

2. Please provide two sachets per lot of the following lots of drug product:
 - a. (b) (4)

3. Please also submit the most recent test results, along with the date of the test, for each of the lots sent.

The samples and reagents should be shipped to:

Al Del Grosso

Food and Drug Administration

Center for Biological Evaluation and Research

Division of Biological Standards and Quality Control

10903 New Hampshire Avenue

WO75, G-717

Silver Spring, MD 20993-0002

Please contact Al Del Grosso at 240-402-9470 (alfred.del-grosso@fda.hhs.gov) or Marie Anderson at 240-402-6292 (marie.anderson@fda.hhs.gov) with questions regarding the shipment.

We request that these samples and documentation be submitted to CBER by February 26, 2016 or notify CBER by then when the shipment can be expected.

Please let me know if you have any questions.

Kind regards,

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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