

From: Houck, Christina M
Sent: Tuesday, January 26, 2016 10:24 AM
To: Kim Sullivan (sullivan@smarthealth.com)
Subject: STN 125579 Information Request

Dear Kim,

We have the following request for additional information for STN 125579:

1. Please submit a formal Priority Name Review request, for Rubber Panel T.R.U.E. TEST, as an amendment to your Biologics License Application STN 125579.

Please see the link below for additional guidance in submitting the Priority Name Review request.

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075068.pdf>

Please let me know if you have any questions.

Kind Regards,

Christina

Christina Houck

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