

From: Houck, Christina M

Sent: Wednesday, April 13, 2016 12:50 PM

To: Kim Sullivan (sullivan@smarthealth.com)

Subject: STN 125579/0 Information Request and Draft PI with CBER's comments

Importance: High

Dear Kim,

We have the following information request for STN 125579/0, as well as the draft PI for STN 125579/0 with CBER's comments.

STN 125579/0 IR:

1. The proposed storage instructions for your Package Insert, carton, and container state "Store Rubber Panel T.R.U.E. TEST (b) (4) 25°C (77°F). Do not freeze." However, the stability data provided in Section 6.2 Storage Conditions, "Stability Study of Rubber Panel Final Report" (Doc. No. 11108, dated September 06, 2011) of your August 19, 2014 amendment do not support your proposed storage conditions. Specifically, the stability studies reported in this amendment were performed at 25°C (b) (4) RH (b) (4) RH for 24 months (long term storage), and at (b) (4) . Based on your stability data and the current (b) (4) definition of controlled room temperature, please revise your package insert, carton, and container to read "Store Rubber Panel T.R.U.E. TEST between 20°–25° (68°–77 °F). Do not freeze."
2. Please define your Date of Manufacture (DOM) for the final Drug Product (DP).

Attached please find the draft PI with CBER's comments. Please submit your revised label to the BLA as an amendment. Please let me know if you have any questions.

Kind Regards,

Christina

Christina Houck

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