Michael J. Smith -S4 Digitally signed by Michael J. Smith -S4 Date: 2022.04.20 10:48:21 -04'00'

From: Smith, Michael (CBER)
Sent: Wednesday, April 20, 2022 10:45 AM
To: Collins, Kathleen Mary Catherine (b) (6)
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Subject: STN 125742/45: IR RE PVP

Kate,

The review team has the below information request regarding the Pharmacovigilance Plan (PVP) that was submitted to STN 125742.45.

In reference to sBLA 125742/45, please revise your Pharmacovigilance Plan (PVP) (Version 1.4, dated December 15, 2021) to include both Tris/Sucrose and PBS/Sucrose formulations. Please submit the combined PVP in an amendment to the efficacy supplement by May 4, 2022, and include a track changes and clean running version.

Regards,

Mike

- Please confirm receipt of this email and let us know if you have any questions.

Mike Smith, Ph.D.
Captain, USPHS

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