From: Smith, Michael (CBER)
Sent: Tuesday, August 17, 2021 6:47 PM
To: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>
Subject: STN 125742.0: IR RE shelf life and date of manufacture

Elisa,

The review team has two questions regarding shelf life and date of manufacture. Please respond as soon as possible and no later than 12:00 PM Wednesday, August 18, 2021.

1. Please send information on what your final, intended drug product shelf life will be and commit to submitting stability data in real time post licensure to support this requested shelf life.
2. Please define your "date of manufacture" for the final, undiluted drug product.

Regards,

Mike

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

Mike Smith, Ph.D.
Captain, USPHS

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