Michael J. Smith -S4
Digitally signed by Michael J. Smith -S4
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=001408 0934, cn=Michael J. Smith -S4
Date: 2022.01.25 11:53:21 -05'00'

From: Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>
Sent: Tuesday, January 25, 2022 11:34 AM
To: Collins, Kathleen Mary Catherine (b) (6); Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>; Mineo, Gosia (b) (6)
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>
Subject: [EXTERNAL] STN 125742/45: IR RE EA/CE and FDA form 356

Kate,

The review team has the below Information Requests (IRs) for you. Please submit your responses in an amendment to STN 125742/45 by February 10, 2022.

1. We noticed that there wasn't any information in the supplement regarding Environmental Assessment (EA) or a claim of categorical exclusion (CE).

   As per 21 CFR 25.15(a), all applications requesting agency action require the submission of an Environmental Assessment (EA) or a claim of categorical exclusion (CE). This includes Biologics License Supplement submissions. Please submit an EA
   or a Claim of CE in an amendment to STN 125742/45 in Module 1.12.14.

2. Please submit a revised FDA form 356h that includes the information regarding all establishments and manufacturing facilities (e.g., including the (b) (4) site).

Regards,

Mike

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

Mike Smith, Ph.D.
Captain, USPHS

Senior Regulatory Review Officer
Food and Drug Administration
Center for Biologics Evaluation & Research
Office of Vaccines Research & Review
Division of Vaccines and Related Products Applications
Tel: 301-796-2640
michael.smith2 fda.hhs.gov