From: Smith, Michael (CBER)
Sent: Friday, June 25, 2021 3:23 PM
To: 'Harkins Tull, Elisa' <Elisa.HarkinsTull@pfizer.com>; 'Aghajani Memar, Neda' <Neda.AghajaniMemar@pfizer.com>; 'Devlin, Carmel M' <Carmel.Devlin@pfizer.com>
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>
Subject: STN 125742.0: IR RE LRP template and samples & reagents

Elisa,

The review team has the below Information Request for you regarding the lot release protocol (LRP) template and samples & reagents.

LRP template IR for STN 125742/0:

Please submit a lot release protocol template for COVID-19 mRNA Vaccine for CBER review by COB Friday, July 9, 2021. Please include the assays performed and acceptance criteria for the drug product.

Sample and Reagent IR for 125742/0:

Drug Substance (DS)
Please provide 50 aliquots (200 µL aliquots preferred) of DS from three different lots and the following reagents in sufficient quantity to perform 50 independent tests for the following DS assays:

1. 5' – Cap assay
i. The current assay control (PF-07305885 DS reference material or equivalent as stated in TM100010578)
(b) (4)

2. Poly(A) Tail
i. The current internal control as stated in TM100010379
(b) (4)

(b) (4)

Drug Product (DP)
Please provide 170 vials of DP per lot from three different DP lots and the following reagents for the following DP release assays:

1. LNP Size
i. Current assay control - an amount (in 3 aliquots) adequate to perform 10 independent tests

2. RNA Encapsulation and RNA Content
i. Reference Standards A and B - 50 vials of each standard or enough to perform 50 tests

3. Lipid identities
i. Reference PF-07302048 - 20 vials
ii. Four (4) lipid standards - 5 grams of each

4. Identity of encoded RNA sequence
50 vials of each reagent OR enough to perform 50 tests
i. Positive PCR Control: PF-07305885 DS or equivalent as stated in TM100010407
ii. Positive (b) (4) Control: PF-07302048 DP or equivalent as stated in TM100010407 (b) (4)
(b) (4)

5. In Vitro Expression Potency assay
i. (b) (4)
ii. Reference Standards, Qualified (b) (4) - 50 vials of each or enough of each to perform 50 tests

6. RNA Integrity

i. (b) (4) Reference Material - 50 vials of each reagent OR enough to perform 50 tests

Documentation

1. Please provide Certificates of Analysis for all reagents
2. Please provide results of the assays listed for the DS lots and DP lots submitted to CBER

The samples and reagents should be shipped to:
Emnet Yitbarek
Food and Drug Administration
Center for Biologics Evaluation and Research
Division of Biological Standards and Quality Control
10903 New Hampshire Avenue
WO75, G-650
Silver Spring, MD 20993

Contact Marie Anderson at 240-402-6292 (marie.anderson@fda.hhs.gov) for questions regarding the request and to provide tracking number of the shipment(s).

We request that these samples, reagents and documentation be sent by July 9, 2021, or notify CBER by then when the shipment(s) can be expected.

Regards,

Mike

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

Mike Smith, Ph.D.
Captain, USPHS

Senior Regulatory Review Officer
Food and Drug Administration

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