From: Smith, Michael (CBER)
Sent: Wednesday, August 18, 2021 4:01 PM
To: Rohlfing, Paul <Paul.Rohlfing@pfizer.com>
Cc: Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>
Subject: RE: [EXTERNAL] FW: STN 125742.0: IR RE shelf life and date of manufacture

Paul,

Regarding your question, we expect that it will be sufficient to provide batched updates within a reasonable period of time after having a group of batches with data to report at 9, 12, 18, and 24 months. You may submit this information as product correspondence or in your annual report, as appropriate for the timing of the collected data. Please comment on when you anticipate sending a post-marketing supplement to extend the expiry dating period and provide a brief description of the information you expect to submit to support that expiry dating period extension.

Regards,

Mike

From: Rohlfing, Paul <Paul.Rohlfing@pfizer.com>
Sent: Wednesday, August 18, 2021 8:36 AM
To: Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>
Cc: Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>
Subject: [EXTERNAL] FW: STN 125742.0: IR RE shelf life and date of manufacture

Mike,

Mike,

Can you clarify what CBER has in mind by "real time"? Taken literally that might be interpreted as reporting each time point, of each lot in the stability program (more than (b) (4) lots at this point. We would not be prepared to make updates that frequently. Updates within a reasonable period of time after having a group of batches with data to report at 12, 18, and 24 months would be more reasonable. Would that be consistent with what CBER is expecting?

Regards,

Paul

From: Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>
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: [EXTERNAL] 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

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
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