

QUERY 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.

Response 1

The final commercial shelf life of the BNT162b2 drug product presently is intended to be 24 months when stored at the intended storage condition of -90 to -60 °C. The Sponsor commits to submitting stability data to support extension of the drug product shelf life beyond the current requested 9-month period at intervals when supporting data are available. Depending on the resulting data, an approximate timetable would be:

<u>Target Expiry Extension</u>	<u>Approximate supplement date</u>
12 Months	February 2021
18 Months	August 2022
24 Months	February 2023

Each submission would contain a Module 2 2.3 Introduction and Module 3 documents (e.g 3.2.P.8.1, 3.2.P.8.3)

Literature References

None

SUPPORTING DOCUMENTATION

New or Replaced Supporting Documentation

None

Previously submitted supporting documentation

None

090177e197d9f93c\Approved\Approved On: 19-Aug-2021 12:49 (GMT)

QUERY 2

Please define your “date of manufacture” for the final, undiluted drug product.

Response 2

The date of manufacture as defined by the Pfizer Kalamazoo manufacturing site is the date of (b) (4)

The date of manufacture as defined by the Pfizer Puurs manufacturing site is the date of the (b) (4)

Across both the Pfizer Kalamazoo and Pfizer Puurs sites, the date of manufacture is no later than the date of (b) (4)

Literature References

None

SUPPORTING DOCUMENTATION

New or Replaced Supporting Documentation

None

Previously submitted supporting documentation

None

090177e197d9f93c\Approved\Approved On: 19-Aug-2021 12:49 (GMT)