U.S. FOOD & DRUG ADMINISTRATION

TELECONFERENCE SUMMARY

Application number:	BLA STN 125742/0
Product name:	COVID-19 Vaccine, mRNA (COMIRNATY)
Proposed Indication:	Active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older
Applicant:	BioNTech Manufacturing GmbH (in partnership with Pfizer, Inc.)
Teleconference date & time:	August 12, 2021; 1:45 – 2:15 PM EDT

FDA Participants:
Marion Gruber, Ph.D.
Mary Malarkey
Ramachandra Naik, Ph.D.

Applicant Participants:
Neda Aghajani Memar
(b) (6)
Donna Boyce
Carmel Devlin
Jennifer Huff
Kevin Nepveux
Amit Patel
Paul Rohlfing
Nicholas Warne

Summary of discussion:
FDA stated that we understand Pfizer has (b) (4) lots ((b) (4) doses) of the COVID-19 vaccine under its control that meet BLA standards except labeling requirements as these lots are currently labeled as EUA material. BLA compliant lots should be available at time of licensure and therefore, these (b) (4) lots need to be identified as licensed material. FDA asked

- what cartons the vaccine vials are packaged in.
- how Pfizer will identify the lots as licensed lots.
- what is the smallest package size Pfizer can put the BLA label on, and how practicably it can be accomplished?
- how Pfizer can relabel vials/cartons without compromising storage conditions?

Pfizer replied that all vials are packaged in (b) (4) vial carton pizza boxes. Pfizer cannot place sticker on the vials or cartons because they are frozen and relabeling vials and cartons would compromise storage conditions. Pfizer is shipping (b) (4) "pizza boxes" in a package and they don't know if Fact Sheets are included in each carton or in the whole package.

Pfizer will submit a proposal on how licensed lots will be identified and draft wording to be used as well as the logistics of how that identification will accompany the (b) (4) lots, shortly

FDA and Pfizer appreciated that availability of both, EUA and licensed lots in the field will be confusing, and discussed ways to mitigate this problem, e.g., by potentially posting the lot numbers of the approved product. Pfizer acknowledged this request and will provide the lot numbers to FDA. FDA added that Package inserts will need to accompany the licensed product that is packaged. This pertains to the (b) (4) lots which are currently under Pfizer's control as well as those lots in the field. Pfizer reminded us that for the EUA material, there is eLabeling, so all doses in the field provide a link to access. Pfizer also indicated that current vaccine turnover is high, and thus, the (b) (4) lots may be used up quickly. Also, Pfizer cannot predict at this time how many lots will be used before the BLA approval. However, Pfizer will get back to FDA with the information tomorrow or so.

FDA asked if Pfizer would continue to manufacture frozen vaccine formulation. Pfizer replied that they are manufacturing frozen vaccine formulation.

FDA asked if the lot numbering system for BLA is the same or it is different than the EUA lot numbering. Pfizer replied that it will likely be the same.

Pfizer committed to provide (1) a proposal on how licensed material will be identified and draft wording to be used and (2) list of vaccine lots that meet licensure standards in the field, to FDA soon. Pfizer also stated that they are planning to submit lot release protocols (LRPs) for the (b) (4) lots by Monday, August 16, 2021.

END