NOTICE OF CLAIMED EXCLUSIVITY

A. BioNTech Manufacturing GmbH hereby requests a determination that the licensure of Pfizer-BioNTech- COVID-19 constitutes the "first licensure" of Pfizer-BioNTech- COVID-19 and that BioNTech Manufacturing GmbH is entitled to exclusivity from the date of licensure pursuant to section 351(k)(7) of the Public Health Service Act.

B. There are no licensed biological products that are structurally related to Pfizer-BioNTech-COVID-19 for which BioNTech Manufacturing GmbH or one of its affiliates, licensors, predecessors in interest, or related entities are the current or previous license holders.

C. Accordingly, consistent with Section 351(k)(7)(C) of the Public Health Service Act, FDA's licensure of Pfizer-BioNTech- COVID-19 under 351(a) will constitute the "first licensure" of Pfizer-BioNTech- COVID-19.

    1. Pursuant to Section 351(k)(7)(A), no approval of an application submitted under Section 351(k) for which Pfizer-BioNTech- COVID-19 is the reference product can be made effective until 12 years after the date of licensure of Pfizer-BioNTech-COVID-19.

    2. Pursuant to Section 351(k)(7)(B), no application under Section 351(k) for which Pfizer-BioNTech- COVID-19 is the reference product can be submitted until 4 years after the date of licensure of Pfizer-BioNTech- COVID-19.