1.3.5.3 EXCLUSIVITY REQUEST

The Sponsor included a claim for reference product exclusivity under section 351(k)(7) of the Public Health Service Act (PHSA) in the original BLA 125742 for COMIRNATY (COVID-19 Vaccine, mRNA).

The Sponsor requests that the FDA apply the reference product exclusivity that was claimed in connection with the first licensure of COMIRNATY to the changes proposed in the COMIRNATY supplemental BLA, which seeks approval of labeling changes related to the administration of COMIRNATY to a new patient population of individuals of 12 years of age and older (i.e. changed from 16 years of age and older). This request for FDA's application of "umbrella exclusivity" in connection with reference product exclusivity is supported by the statute, FDA's draft guidance on reference product exclusivity, and an Agency precedent.

The applicable statute provides that reference product exclusivity starts on the "date on which the reference product was first licensed under subsection (a)" of PHSA section 351 and indicates that the date of approval of a supplemental BLA is not a new date of first licensure.[1]

In the draft guidance, FDA has suggested that a supplemental BLA that is ineligible for its own period of reference product exclusivity nonetheless may be eligible for umbrella exclusivity. For example, FDA has stated that "[a] biological product submitted for licensure under section 351(a) of the PHS Act (a 351(a) application) may be eligible for a period of exclusivity that commences on the date of its licensure unless its date of licensure is not considered a date of first licensure because it falls within an exclusion under 351(k)(7)(C)." This sentence suggests that a supplemental BLA (which falls within the referenced exclusion) would remain eligible for reference product exclusivity, although the exclusivity period would commence on the date of first licensure (in general, the date of approval of the original BLA) rather than on the approval date of the supplement.[2]

Finally, a precedent in the Purple Book database indicates that the FDA is applying umbrella exclusivity to supplemental BLAs. The Purple Book reflects that both the original BLA 125285 for FLUBLOK (influenza vaccine) (approved on January 16, 2013) and a supplement to that BLA (approved on October 7, 2016) share the same first licensure date of January 16, 2013, the approval date of the original BLA. The Purple Book further reflects that reference product exclusivity expires on January 16, 2025 for both the original BLA and the supplement. Similarly, the reference product exclusivity that earned in connection with the approval of the original BLA for COMIRNATY should cover the COMIRNATY supplemental BLA.

The Sponsor therefore requests that FDA apply umbrella exclusivity to this supplemental BLA for COMIRNATY. Accordingly, FDA should not approve any biosimilar application

[1] PHSA § 351(k)(7).

[2] FDA, Draft Guidance for Industry, *Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act* (Aug. 2014), at 3-5 (noting that when a product's licensure date is not considered the date of first licensure, that product does not receive a "new period of exclusivity," a "separate period" of exclusivity, or "its own period of exclusivity").

referencing BLA 125742, and seeking approval for the changes proposed in this supplemental BLA, until 12 years after COMIRNATY's first licensure date.