FDA recognizes the urgency of developing a vaccine to prevent COVID-19 and has provided expedited feedback to vaccine manufacturers who are developing preventive vaccines against COVID-19. FDA is also providing regulatory guidance to federal partners within HHS, including the National Institutes of Health (NIH) and the Biomedical Advanced Research and Development Authority (BARDA), that are supporting efforts to develop vaccines to prevent COVID-19.

5.0 Selected U.S. legal requirements for demonstrating safety and effectiveness of biological products to support licensure

To help expedite the development and availability of safe and effective COVID-19 vaccines, FDA has been working closely with vaccine developers by providing timely regulatory advice regarding data needed to demonstrate the safety and effectiveness of COVID-19 vaccines and providing technical assistance regarding COVID-19 vaccine manufacturing and scale-up activities. For FDA licensure, a single set of regulatory requirements applies to all vaccines, regardless of the technology used to produce them. Section 351 of the Public Health Service Act (42 U.S.C. 262) states that a biologics license application shall be approved based on a demonstration that "…(I) the biological product that is the subject of the application is safe, pure and potent; and (II) the facility in which the biological product is manufactured, processed, packed or held meets standards designed to assure that the biological product continues to be safe, pure, and potent..." (5). Thus, regardless of indication or intended target population, only those COVID-19 vaccines that are demonstrated to be safe and effective, and that can be manufactured in a consistent manner, will be licensed by the FDA.

6.0 U.S. legal requirements to support issuance of an EUA for a biological product

Based on the declaration by the Secretary of HHS that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19, FDA may issue an EUA after FDA has determined that certain statutory requirements are met (see section 564 of