

the FD&C Act (21 U.S.C. 360bbb-3) and FDA guidance for industry, “Emergency Use Authorization of Medical Products and Related Authorities” (January 2017)) (6,7). Through an Emergency Use Authorization (EUA), FDA can authorize the emergency use of unapproved medical products (or unapproved uses of approved medical products) to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by threat agents, such as COVID-19, when there are no adequate, approved, and available alternatives. In order to issue an EUA for a medical product, FDA must determine, among other things, that the product may be effective in diagnosing, treating, or preventing serious or life-threatening diseases or conditions caused by the agent(s) identified in the EUA declaration, and that the known and potential benefits of the product, when used to diagnose, prevent, or treat such serious or life-threatening disease or condition, outweigh its known and potential risks of the product.

In evaluating whether to issue an EUA request for a COVID-19 vaccine, FDA would necessarily take into account the unique considerations posed by an investigational COVID-19 vaccine, including risk and benefit considerations. Vaccines are complex biological products, and an EUA for a COVID-19 vaccine may allow for rapid and widespread deployment for administration of the vaccine to millions of individuals, including healthy people. Issuance of an EUA for a COVID-19 vaccine would require adequate manufacturing information to ensure its quality and consistency and a determination by FDA that the vaccine’s benefits outweigh its risks based on data from at least one well-designed Phase 3 clinical trial that demonstrates the vaccine’s safety and efficacy in a clear and compelling manner. Any assessment regarding an EUA would need to be made on a case-by-case basis considering the target population, the characteristics of the product, the preclinical and human clinical study data on the product, and the totality of the available scientific evidence relevant to the product.

## **7.0 FDA guidance for industry and advice to individual sponsors regarding COVID-19 vaccine licensure and authorization**

FDA is committed to providing a level playing field for sponsors on regulatory issues and has provided detailed advice regarding the development of COVID-19 vaccines in a June 2020 guidance document (“Development and Licensure of Vaccines to Prevent COVID-19”) and in communications with individual sponsors regarding their specific development programs.