February 19, 2021

Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.
Siri Glimstad
200 Park Avenue
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New York, NY 10166

Dear Mr. Siri and Ms. Brehm,

Thank you for your January 5, 2021, inquiry pertaining to the safety of the mRNA vaccines to prevent COVID-19 authorized for emergency use by FDA in December 2020.

For both authorized COVID-19 vaccines, FDA has evaluated and analyzed the safety and effectiveness data from clinical trials conducted in tens of thousands of study participants and manufacturing information submitted by the companies. These clinical trials are being conducted according to the rigorous standards set forth by FDA. FDA has determined that the totality of the available data provides clear evidence that both vaccines may be effective in preventing COVID-19 and support that the known and potential benefits outweigh the known and potential risks of the vaccine's use in millions of people, including healthy individuals.

The reactogenicity profile of both vaccines is well described in documents available on the FDA website (https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine and https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine).

FDA must ensure that recipients of a vaccine under an emergency use authorization (EUA) are informed, to the extent practicable given the applicable circumstances, that FDA has authorized the emergency use of the vaccine, of the significant known and potential benefits and risks, the extent to which such benefits and risks are unknown, that they have the option to accept or refuse the vaccine, and of any available alternatives to the product. Typically, this information is communicated in a patient "fact sheet." FDA posts these fact sheets on our website.

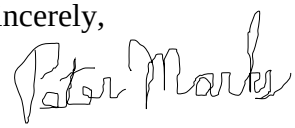
The issuance of an EUA is different than an FDA approval (licensure) of a vaccine, in that a vaccine available under an EUA is not approved. In determining whether to issue an EUA for a product, FDA evaluates the available evidence to determine whether the product may be effective and also assesses any known or potential risks and any known or potential benefits. If the benefit-risk assessment is favorable, the product is made available during the emergency.

According to the Centers for Disease Control and Prevention (CDC), as of February 18, 2021, over 41 million people in the United States have received at least one dose of a vaccine to prevent COVID-19, a disease that is causing vast numbers of hospitalizations and deaths in the United States each day and

for which there are limited treatments available. Among people who have received a vaccine available under an EUA and who have reported side effects, the majority of the side effects reported reflect those that were observed in clinical trials and that are conveyed in the Fact Sheet for Recipients and Caregivers and the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers).

For both COVID-19 vaccines authorized under an EUA, ongoing clinical trials will continue to obtain additional safety and effectiveness information intended to support eventual approval (licensure). In addition, as a condition of authorization for each of these COVID-19 vaccines, the manufacturer will conduct post-authorization observational studies to evaluate the association between the vaccine and pre-specified adverse events of special interest, along with deaths and hospitalizations. Conditions of authorization also include requirements for the manufacturers and vaccination providers to report certain adverse events to the Vaccine Adverse Event Reporting System and for the manufacturers to submit periodic safety reports to FDA. Further, FDA, CDC, and other federal partners are using robust systems and data sources to conduct ongoing safety monitoring for COVID-19 vaccines authorized under an EUA.

Sincerely,



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