

October 18, 2022

Fatima Khan

(b) (6)

Re: Citizen Petition (Docket Number FDA-2022-P-0677)

Sent via email to: fatima@protecttheirfuture.org

Dear Ms. Khan,

This letter responds to the citizen petition dated April 25, 2022 that you submitted to the Food and Drug Administration (FDA, the Agency, we) on behalf of yourself and other signatories (Petitioner) relating to: Emergency Use Authorizations (EUAs) of vaccines to prevent Coronavirus Disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals between the ages of six months and under 6 years of age (the Petition).

In the Petition, Petitioner requests that: “FDA immediately and expeditiously review and act on any EUA application for a COVID-19 vaccine for children between the ages of six months and under six years, without delay.”¹ At the time the Petition was submitted, FDA had authorized the use of the Pfizer-BioNTech COVID-19 Vaccine for individuals 5 years and older, but no COVID-19 vaccine was authorized or approved for use in individuals younger than 5 years of age.² The Petition makes reference to news reports that were published prior to the submission of the Petition regarding potential requests from Pfizer Inc. (Pfizer)³ and ModernaTX, Inc. (Moderna) to revise the companies’ EUAs to authorize use of their COVID-19 vaccines in the younger pediatric population, down to 6 months in age.⁴ We therefore interpret the Petition as requesting that FDA “immediately and expeditiously review and act on” a potential EUA request by Pfizer and/or Moderna for use of their COVID-19 vaccine(s) in this younger pediatric population.⁵

¹ Petition at 2.

² At the time the Petition was submitted, the COVID-19 vaccines produced by other manufacturers were authorized or approved by FDA for use in individuals 18 years of age and older and not in the pediatric population.

³ See, e.g., Petition at 4. (“Then, in late January 2022, the FDA requested that Pfizer submit an EUA request for 2 doses while it continued to test a 3rd dose.”)

⁴ See, e.g., Petition at 5. (“On April 20, 2022, Moderna stated that it planned to file an EUA application by the end of the month.”)

⁵ The Petition requests that FDA take this action for a COVID-19 vaccine “for children between the ages of six months and under six years.” Because at the time of submission of the Petition the Pfizer-BioNTech COVID-19

On June 17, 2022 FDA revised the EUA for the Pfizer-BioNTech COVID-19 Vaccine to authorize use of the vaccine for prevention of COVID-19 caused by SARS-CoV-2 in individuals 6 months and older.⁶ That same day, FDA also revised the EUA for the Moderna COVID-19 Vaccine to authorize use of the vaccine for prevention of COVID-19 in individuals 6 months and older.⁷ For both EUA revisions, FDA authorized age-appropriate presentations of the vaccines for use in these pediatric populations.

Given the revisions to the EUAs for the Pfizer-BioNTech COVID-19 Vaccine and the Moderna COVID-19 Vaccine since you submitted the Petition, we conclude that the circumstances since the date you submitted your Petition have rendered your Petition moot. Accordingly, we are dismissing your citizen petition in accordance with 21 CFR 10.30(e).

Sincerely,

A handwritten signature in black ink that reads "Peter Marks". The signature is fluid and cursive, with the first name "Peter" and last name "Marks" clearly distinguishable.

Peter Marks, MD, PhD
Director
Center for Biologics Evaluation and Research

cc: Dockets Management Staff

Vaccine was already authorized for use in individuals 5 years of age and older, we interpret the Petition's request as it relates to the Pfizer-BioNTech COVID-19 Vaccine as requesting that FDA authorize use of the vaccine in individuals 6 months through 4 years of age, rather than individuals through 5 years of age.

⁶ As discussed above, the EUA for the Pfizer-BioNTech COVID-19 Vaccine was already authorized for use in individuals 5 years and older. The June 17 authorization expanded the pediatric populations authorized to receive the vaccine to include individuals 6 months through 4 years of age.

⁷ Prior to the June 17 authorization, the Moderna COVID-19 Vaccine was authorized for use in individuals 18 years of age and older. The June 17 revision of the EUA provided for the use of different presentations of the vaccine in the following younger age cohorts: one presentation for use in individuals 6 months through 5 years of age; one presentation for use in individuals ages 6 years through 11 years of age; and one presentation for use in individuals 12 through 17 years of age.