



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Silver Spring MD 20993

January 21, 2022

Carol Taccetta

(b) (6)

Sent via email to: [ctaccetta2020@gmail.com](mailto:ctaccetta2020@gmail.com)

Dear Petitioner:

Your submission requesting the Commissioner of Food and Drug Administration immediately execute the items listed for the protection of the vulnerable subpopulations of pregnant women, fetuses and children, per 45 CFR 46:

- 1) Revoke all Covid-19 vaccine Biologics License Application (BLA) approvals and emergency use authorizations (EUA) for all pediatric subgroups, ages 0 to 17.
- 2) Add Pregnancy as a Contraindication for all Covid-19 vaccine BLAs and EUAs.
- 3) Immediately suspend all ongoing clinical trials for all pediatric and pregnant subpopulations.
- 4) Add pregnancy and pediatric exclusion criteria for all ongoing or planned Covid-19 vaccine clinical trials.

Your petition was received and processed under CFR 10.30 by this office on 01/20/2022 and was assigned docket number FDA-2022-P-0086. Please refer to this docket number in future correspondence on this subject with the Agency.

Also, note that the acceptance of the suitability petition for filing is a procedural matter and in no way reflects the agency's decision on the substantive merits of the petition.

Sincerely,

Karen Malvin  
Acting Director  
Dockets Management Staff  
FDA/Office of Operations (OO)