

From: Robert F. Kennedy Jr. <robert.kennedyjr@childrenshealthdefense.org>

Sent: Friday, September 25, 2020 6:02 PM

To: FDA Commissioner <Stephen.Hahn@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>

Cc: Congressman Posey <rockledger@aol.com>; Buchanan, Lisa K (OS) <Lisa.Buchanan@hhs.gov>; senator@kaine.senate.gov; Doepel, Laurie K (NIH) <laurie.doepel@nih.gov>; Fauci, Anthony S (NIH) <afauci@niaid.nih.gov>; hugh.auchincloss@nih.gov; john.mascola@nih.gov; cliff.lane@nih.gov

Subject: Letter from RFK, Jr. on concerns with Moderna's COVID vaccine

Drs. Hahn and Marks,

I'm writing to you today regarding Moderna's mRNA vaccine in development that contains polyethylene glycol (PEG). The use of PEG in drugs and vaccines is increasingly controversial due to the well-documented incidence of adverse PEG-related immune reactions, including life-threatening anaphylaxis. Roughly seven in ten Americans may already be sensitized to PEG, which may result in reduced efficacy of the vaccine and an increase in adverse side effects. It is critical that FDA's regulatory scrutiny of Moderna be beyond reproach, since other manufacturers will look to Moderna as a role model for their own safety studies. FDA's review of Moderna's vaccine should be a template for rigorous protocols that unambiguously elevate safety above political or monetary considerations. I urge that you give priority to your agency's duty to protect public health and the rights of trial participants to genuine informed consent regarding the use of PEG in. We ask you to order Moderna to immediately inform all trial participants of the risk for allergic reactions from PEG, and to carefully monitor and publicly disclose allergic reactions potentially associated with PEG.

Please see the attached for more information.

Sincerely,

Robert F. Kennedy, Jr.