



☆ **McNeill, Lorrie** 

 Inbox -...defense.org

December 2, 2020 at 3:56 PM

LM 

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

To: robert.kennedyjr@childrenshealthdefense.org

Dear Mr. Kennedy,

This is in response to your letter to Commissioner Hahn and Dr. Peter Marks regarding Moderna's investigational mRNA vaccine for the prevention of COVID-19. I apologize for the delay in responding.

Thank you for sharing your comments regarding Moderna's vaccine and FDA's review process for this and other COVID-19 vaccines.

FDA is a science-based regulatory agency and is focused on ensuring that vaccines that are approved or authorized for use are supported by the best available scientific and clinical evidence and that the statutory requirements for safety and effectiveness are met. In this regard, FDA is using all appropriate regulatory authorities and providing scientific and regulatory advice to facilitate the development and availability of safe and effective therapeutics and vaccines to address COVID-19.

We recommend that you reach out to Moderna directly to inquire about the informed consent for the firm's investigational COVID-19 vaccine.

Thank you again for contacting FDA.

Best regards,

Lorrie H. McNeill

Director

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