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November 9, 2022

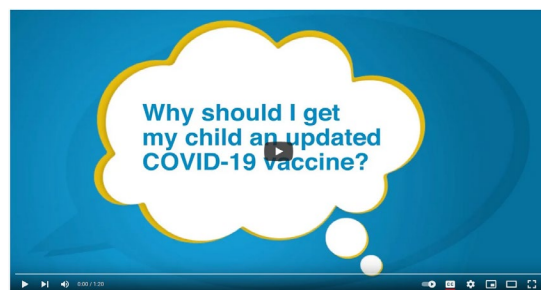
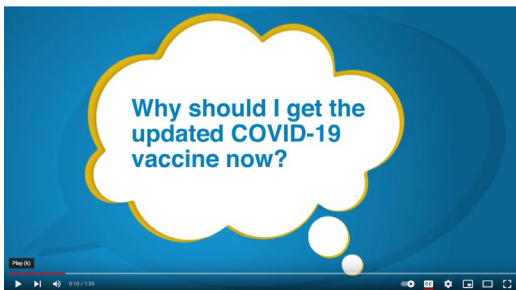
VIA EMAIL AND FED EX

Dr. Peter Marks
Director, Center for Biologics
Evaluation and Research
U.S. Food and Drug Administration
10903 N.H. Ave. W071-3128
Silver Spring, MD 20993-0002
peter.marks@fda.hhs.gov

Re: *FDA videos of November 3, 2022 and November 7, 2022 – Failure to Meet Required Conditions of Emergency Use Authorizations*

Dear Director Marks:

On behalf of Informed Consent Action Network (“ICAN”), we write regarding two recently released videos in your *Just a Minute* series, namely the November 3, 2022 video titled “Why should I get the updated COVID-19 vaccine now?”¹ and the November 7, 2022 video titled “Why should I get my child an updated Covid-19 vaccine?”² The videos are in violation of both Pfizer’s³ and Moderna’s⁴ emergency use authorizations (“EUA”) as the videos fail to meet the required “Conditions Related to Printed Matter, Advertising, and Promotion.”



¹ <https://www.youtube.com/watch?v=5kL9PIyru1w>.

² <https://www.youtube.com/watch?v=XW5Ts0wtbGY>.

³ See <https://www.fda.gov/media/150386/download> at 28-29.

⁴ See <https://www.fda.gov/media/144636/download> at 26-27.

Because these videos lack the language required by the Food and Drug Administration's EUA conditions for Pfizer's and Moderna's bivalent COVID-19 vaccines, we request their immediate removal.

As provided in the EUA for each:

All descriptive printed matter, advertising, and **promotional material** relating to the use of the [Pfizer-BioNTech and Moderna] COVID-19 Vaccine **clearly and conspicuously shall state, as applicable**, that:

- The [Pfizer-BioNTech COVID-19 Vaccine, Bivalent] Moderna COVID-19 Vaccine, Bivalent has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals [5 for Pfizer, 6 for Moderna] years of age and older; and
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner⁵

Because the videos are “promotional material,” which both advertise and promote Pfizer's and Moderna's EUA Bivalent COVID-19 vaccines, they are required to contain this language.

ICAN requests that you, as the Director of the Center for Biologics Evaluation and Research, immediately remove these videos and explain why a Director within the FDA would violate its own EUA conditions. ICAN looks forward to your prompt response.

Very truly yours,



Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.

cc: Commissioner Robert Califf – commissioner@fda.hhs.gov
Inspector General Christi A. Grimm - Christi.Grimm@oig.hhs.gov
Office of Regulatory Affairs at FDA Ombudsman –
Erica Katherine ORAmbudsman@fda.hhs.gov

⁵ See <https://www.fda.gov/media/144636/download> at 26-27 (emphasis added); see also <https://www.fda.gov/media/150386/download> at 28-29 (emphasis added).