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VIA EMAIL AND FEDEX

April 13, 2023

Lisa Stockbridge, PhD
Branch Chief
Advertising and Promotional Labeling
Food and Drug Administration
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FDA/CBER
OCBQ/DCM/APLB
10903 New Hampshire Avenue
WO Building 71
Silver Spring, MD 20993

Re: Violation of EUAs in Pfizer's and Moderna's Promotional Videos Advertising COVID-19 Vaccines

Dear Branch Chief Stockbridge and FDA/CBER:

On behalf of Informed Consent Action Network ("ICAN"), we write requesting your intervention concerning multiple illegal advertisements from Pfizer and Moderna concerning their COVID-19 vaccines and boosters.

I. Emergency Use Authorization Requirements and Federal Regulation

As you are surely aware, Pfizer's and Moderna's boosters are currently only authorized for emergency use, as are all Pfizer COVID-19 vaccines for children under twelve, and Moderna's COVID-19 vaccines for children, which subjects these products to strict advertising regulations. Pfizer's Emergency Use Authorization ("EUA") requires:

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

- **The Pfizer-BioNTech COVID-19 Vaccine 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 12 years of age and older, in individuals 5 through 11 years of age, or in individuals 6 months through 4 years of age as appropriate; or

- **The Pfizer-BioNTech 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 12 years of age and older, in individuals 5 through 11 years of age, or in individuals 6 months through 4 years of age as appropriate; 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 sooner.¹

Moderna's EUA requires the same.² Additionally, advertisements for investigational products are subject to 21 CFR § 312.7(a), which states, in pertinent part:

A sponsor or investigator, or any person acting on behalf of a sponsor or investigator, shall not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug. [The] intent [of this provision] is to restrict promotional claims of safety or effectiveness of the drug for a use for which it is under investigation and to preclude commercialization of the drug before it is approved for commercial distribution.

II. **"Got Booster" Advertisement**

A commercial titled "*Got Booster?*" recently began airing in late January 2023 and features celebrity Martha Stewart sharpening a Samurai sword as she explains to the audience that she received the COVID-19 booster "designed to protect against recent Omicron variants."³ The video concludes with Ms. Stewart violently slicing off the top of a pineapple with the sword and exposing a bandage on her upper arm while asking "Got Booster?" -- presumably a play on the popular *Got Milk?* marketing campaign from the early 1990s.⁴ The advertisement concludes with Pfizer and BioNTech's logos appearing on the screen. Pfizer Inc. is listed as the "ad company."

¹ <https://www.fda.gov/media/150386/download> at 31 (emphasis added).

² <https://www.fda.gov/media/144636/download> at 29.

³ <https://www.youtube.com/watch?v=YtFIRROCS1s>.

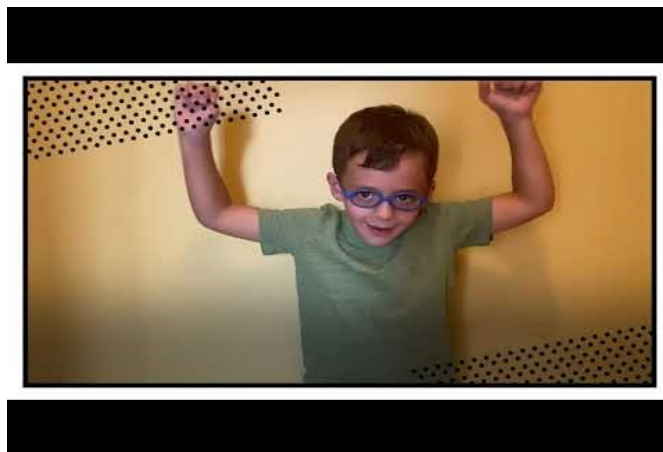
⁴ <https://www.gotmilk.com>.



Crucially, the advertisement does not contain the EUA-required disclaimer language indicating that Pfizer’s booster is not yet approved or licensed by the FDA. Furthermore, this advertisement is in clear violation of 21 CFR § 312.7(a) as it is promoting the safety and effectiveness of an investigational product by a celebrity on behalf of Pfizer, the sponsor.

III. “Thank you! 5-11-year-old Covid-19 Vaccine Clinical Trial Volunteers”

We additionally write regarding Pfizer’s November 1, 2021 advertisement titled, “Thank you! 5-11-year-old Covid-19 Vaccine Clinical Trial Volunteers,” which was regularly aired during the children’s program *Sesame Street* beginning in November 2021.⁵



This advertisement, which consists of a string of emotionally evocative scenes of young children dressed as superheroes, states that children who participated in the COVID-19 vaccine clinical trials are “brave superheroes” because they “help the whole entire world fight Coronavirus” with their “ability to save people.” Although structured as a “thank you” to child clinical trial participants, it clearly serves as an advertisement for the product and therefore is in violation of 21 CFR § 312.7(a).

⁵ https://www.youtube.com/watch?v=Xm_gLd7MjP0.

IV. Numerous Other Pfizer and Moderna Advertisements Violate the Law and EUAs

Unfortunately, the above-mentioned advertisements are not the only ones that violate the terms of an EUA and 21 CFR § 312.7(a). Both Pfizer and Moderna have recently issued numerous other advertisements for EUA products that promote their investigational products and fail to include the necessary disclaimer language, including the following:

Pfizer:

- “Legendary Voice” featuring John Legend - Employs singer John Legend to promote updated boosters.⁶
- “Protected On Tour” featuring Charlie Puth - Employs Singer Charlie Puth to promote updated boosters.⁷
- “The World Keeps Changing” - Promotes updated boosters.⁸
- “College Basketball: Updated Boosters” - Promotes updated boosters.⁹
- “COVID-19 Boosters Shots” - Promotes “new” boosters.¹⁰
- “More” - Promotes boosters designed for COVID-19 variants.¹¹

Moderna:

- “Get Boosted This Fall” - Promotes “updated” boosters to “protect against multiple variants.”¹²
- “What are Booster Shots” - Promotes “updated bivalent COVID-19 boosters [] designed to boost protection against multiple COVID-19 variants.”¹³
- “Make It Yours” - Promotes COVID-19 Boosters available “for millions.”¹⁴

* * *

Because these promotional materials fail to meet the required conditions set forth in the respective EUAs for Pfizer’s and Moderna’s COVID-19 vaccines and boosters and because they violate the federal regulation detailed above, we request prompt corrective action. ICAN requests that the FDA Advertising and Promotional Labeling branch accept this letter as a formal complaint,

⁶ <https://www.ispot.tv/ad/1YLb/pfizer-inc-legendary-voice-featuring-john-legend>.

⁷ <https://www.ispot.tv/ad/29oq/pfizer-inc-protected-on-tour-featuring-charlie-puth>.

⁸ <https://www.ispot.tv/ad/1YH9/pfizer-inc-the-world-keeps-changing>.

⁹ <https://www.ispot.tv/ad/2iuA/pfizer-inc-college-basketball-updated-boosters>.

¹⁰ <https://www.ispot.tv/ad/2y2h/pfizer-inc-covid-19-booster-shots>.

¹¹ <https://www.ispot.tv/ad/2YX5/comirnaty-more>.

¹² https://www.ispot.tv/ad/2AZ_/moderna-get-boosted-this-fall.

¹³ <https://www.ispot.tv/ad/2BhD/moderna-what-are-booster-shots>.

¹⁴ <https://www.ispot.tv/ad/qPrA/moderna-make-it-yours>.

promptly review this promotional material, and commence a compliance action against Pfizer and Moderna demanding the immediate removal of the advertisements. We look forward to your prompt response.

Very truly yours,

A handwritten signature in blue ink, appearing to be 'A. Siri', written in a cursive style.

Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.
Catherine Cline, Esq.
Dana Smith, Esq.