U.S. FOOD & DRUG ADMINISTRATION

September 22, 2021

Aaron Siri
Siri & Glimstad, LLP
200 Park Avenue, 17th Floor
New York, NY 10166

Sent via email to: aaron@sirillp.com

Re: Docket No. FDA-2021-P-0337

Dear Mr. Siri:

I am writing to inform you that the Food and Drug Administration (FDA, we) has not yet reached resolution of the issues raised in your citizen petition on behalf of Informed Consent Action Network, received by the Dockets Management Staff on March 29, 2021. In your petition, you request that FDA take certain actions with respect to enforcement of the conditions in the emergency use authorizations (EUAs) for COVID-19 vaccines. Specifically, you request FDA to take the following actions:

1. Provide public notice to all state health departments, major health insurance carriers, major health systems, and other stakeholders that they are to comply with the following "conditions of authorization" in the EUAs and in 21 U.S.C. § 360bbb-3(e), including that:

    a. "All descriptive printed matter, advertising, and promotional material, relating to the use of the [] COVID-19 Vaccine[s] shall be consistent with the authorized labeling, as well as the terms set forth in [each] EUA, and meet the requirements set forth in section 502(a) and (n) of the FD&C Act and FDA implementing regulations;"

    b. "All descriptive printed matter, advertising, and promotional material relating to the use of the Janssen COVID-19 Vaccine clearly and conspicuously shall state that: This product 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 18 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 sooner;" and

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c. "[I]ndividuals to whom the product is administered are informed of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks."

2. Ensure that each manufacturer of an FDA-authorized COVID-19 vaccine is complying with the requirement to "ensure that the terms of [its] EUA are made available to all relevant stakeholders," by requiring each to provide the FDA with a written list of the stakeholders to whom the manufacturer has notified of the terms of the EUA and provide a copy of the form of the notification sent by the manufacturer.

3. Ensure that emergency response stakeholders are complying with the FDA's requirement that "[e]mergency response stakeholders will ensure that vaccination providers within their jurisdictions are aware of [the EUA] letter of authorization, and the terms [t]herein," by notifying emergency response stakeholders of this obligation and requesting they each submit to the FDA notification of the steps taken to comply with this requirement.

Because of the existence of other FDA priorities, we have not been able to reach a decision on the petition at this time. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Peter Marks, MD, PhD
Director
Center for Biologics Evaluation and Research

cc: Dockets Management Staff