August 26, 2022

Sarah Lieber
Sanofi Pasteur Inc.
1 Discovery Drive
Swiftwater, PA 18370

Sent via email to: michele.deangelo@sanofi.com; sarah.lieber@sanofi.com

Re: Docket No. FDA-2022-P-0270

Dear Ms. Lieber,

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 received by the Dockets Management Staff on March 2, 2022. In your petition, you requested that FDA require Seqirus to amend the labeling for its influenza vaccine products Fluad and Fluad Quadrivalent in a manner consistent with FDA regulations, guidance documents, and precedents. In particular, you requested that the labeling for these products, both of which received accelerated approval, contain a description of the limitations of existing evidence, including a description of results from an absolute efficacy confirmatory study that failed to meet its primary efficacy endpoints.

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's 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

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

cc: Dockets Management Staff