March 2, 2022

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

Sent via email to: michele.deangelo@sanofi.com; Sarah.Lieber@sanofi.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug to require Seqirus to amend the labeling for its influenza vaccine products Fluad and Fluad Quadrivalent in a manner consistent with FDA regulations, in particular, requesting 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 was received and processed under CFR 10.30 by this office on 03/02/2022.

It was assigned docket number FDA-2022-P-0270. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2022.03.03 12:27:28 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)