Our STN: BL 125510/219 **ASSIGN / APPROVE**

Seqirus Inc. December 4, 2020
Attention: Peggy Charpie, M.S.
50 Hampshire Street, 9th floor
Cambridge, MA 02139

Dear Ms. Charpie:

Submission Tracking Number (STN) BL125510/219 has been assigned to your recent supplement to your Biologics License Application (BLA) for Influenza Vaccine, Adjuvanted (Fluad Quadrivalent) submitted and received November 4, 2020. Your submission is in the form of a "Supplement – Changes Being Effected" as described under 21 CFR 601.12(c)(5).

We approved your request to supplement your Biologics License Application for Influenza Vaccine, Adjuvanted (Fluad Quadrivalent) to include corrections to Section 8.4 Pediatric Use of the package insert labeling.

Please submit the final content of labeling (21 CFR 601.14) in SPL format via the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

You may submit two draft copies of the proposed introductory advertising and promotional labeling with an FDA Form 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertisement and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes this change.

We will include information contained in the above-referenced supplement in your BLA file.

If you have any questions, please contact the Regulatory Project Manager, Brenda Baldwin, PhD, at 301-796-2640.

Sincerely,

Doran L. Fink, M.D., Ph.D.
Deputy Director - Clinical
Division of Vaccines and
Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research