Our STN: BL 125510/191

SUPPLEMENT APPROVAL
PMR FULFILLED

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

October 28, 2020

Dear Ms. Charpie:

We have approved your request submitted and received April 28, 2020, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Influenza Vaccine, Adjuvanted (Fluad and Fluad Quadrivalent) manufactured at your Holly Springs, NC facility to include revisions to the package insert labeling to update Section 8.4, Pediatric Use.

The review of this supplement was associated with the following National Clinical Trial (NCT) numbers: NCT02587221 and NCT03314662.

LABELING

We hereby approve the draft package insert labeling submitted under amendment 1, dated October 16, 2020.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (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.

The SPL will be accessible via publicly available labeling repositories.

All final labeling should be submitted as Product Correspondence to this BLA 125510 at the time of use (prior to marketing) and include implementation information on Form FDA 356h.

ADVERTISING AND PROMOTIONAL LABELING

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 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 advertising 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 these changes.

FULFILLED POSTMARKETING REQUIREMENTS

This submission fulfills your postmarketing requirements (PMRs 2 and 3) identified in the November 24, 2015, approval letter for BLA STN 125510/0 (and PMR 2 identified in the February 21, 2020, approval letter for BLA STN 125510/143) for Influenza Vaccine, Adjuvanted. The requirements addressed in this submission are as follows:

2. Deferred pediatric trial (V118_05) under PREA to evaluate the efficacy, safety and immunogenicity of Fluad (aQIV) when administered to children 6 months to less than 72 months of age.

3. Deferred pediatric trial (V70_29) under PREA to evaluate the safety and immunogenicity of Fluad when administered to children 6 months to less than 72 months of age.

PEDIATRIC REQUIREMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and

effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We note that you have fulfilled the pediatric study requirements for all relevant pediatric groups for this application.

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

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