Our STN: BL 125408/351

SUPPLEMENT APPROVAL
PMR FULFILLED

Seqirus, Inc.
Attention: Ruben Ojeda
475 Green Oaks Parkway
Holly Springs, NC 27540

October 14, 2021

Dear Mr. Ojeda:

We have approved your request, submitted and received December 14, 2020, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Influenza Vaccine (FLUCELVAX), to extend the use of FLUCELVAX QUADRIVALENT manufactured at your Holly Springs, NC; (b) (4) facilities, to persons 6 months of age and older.

The review of this supplement was associated with the following National Clinical Trial (NCT) number: NCT04074928

LABELING

We hereby approve the draft content of labeling Package Insert submitted under amendment 8, dated October 8, 2021 and the draft carton and container labels submitted under amendment 7, dated September 20, 2021.

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. Content of labeling must be identical to the Package Insert submitted on October 8, 2021. 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.

CARTON AND CONTAINER LABELS

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on September 20, 2021, according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain*

Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 125408 at the time of use 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 REQUIREMENT/COMMITMENTS

This submission fulfills your postmarketing requirement (PMR #2) identified in the May 23, 2016, approval letter for BLA STN BL 125408/127 for Influenza Vaccine. The requirement addressed in this submission is as follows:

2. Deferred pediatric study (Study V130_10) under PREA to evaluate the safety and immunogenicity of your quadrivalent formulation of Influenza Vaccine in pediatric subjects 6 months to < 4 years of age.

   Final Protocol Submission: June 30, 2019

Study/Trial Completion: August 30, 2020

Final Report Submission: February 28, 2021

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 requirement for all relevant pediatric age 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