Our STN: BL 125408/329

SUPPLEMENT APPROVAL
PMR FULFILLED

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

March 3, 2021

Dear Ms. Charpie:

We have approved your request submitted and received on March 31, 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 and (b) (4) facilities to persons 2 years of age and older.

We approved BLA STN 125408/127 on May 23, 2016, under 21 CFR 601 Subpart E for Accelerated Approval of Biological Products for Serious or Life-Threatening Illnesses. Approval of this supplement fulfills the following postmarketing requirement for use in persons 4 years to <18 years of age made under 21 CFR 601.41:

FULFILLED ACCELERATED APPROVAL REQUIRED STUDIES

1. To conduct a study to evaluate the efficacy, safety and immunogenicity of the quadrivalent formulation of your Influenza Vaccine compared to a non-influenza comparator vaccine in persons 4 years to <18 years of age.

   Final Protocol Submission: September 30, 2016

   Study/Trial Completion: March 30, 2017

   Final Report Submission: August 30, 2018

The review of this supplement was associated with the following National Clinical Trial (NCT) numbers: NCT03165617.

LABELING

We hereby approve the draft package insert labeling submitted under amendment #10, dated February 9, 2021, the draft carton labeling submitted under amendment #11, dated February 19, 2021, and draft container labeling submitted under amendment 8, dated October 15, 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.

PACKAGE AND CONTAINER LABELS

Please electronically submit final printed package and container labels that are identical to the package and container labels submitted on February 19, 2021 and October 15, 2020, 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 125408 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.

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 remind you that your deferred pediatric study required under section 505B(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) is a required postmarketing study. The status of this postmarketing study must be reported according to 21 CFR 601.28 and section 505B(a)(3)(B) of the FDCA. In addition, section 506B of the FDCA and 21 CFR 601.70 require you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

Label your annual report as an **Annual Status Report of Postmarketing Study Requirement/Commitments** and submit it to the FDA each year within 60 calendar days of the anniversary date of the approval of BLA STN 125408 until all requirements and commitments subject to the reporting requirements under section 506B of the FDCA are released or fulfilled. This required study, as identified in the May 23, 2016 approval letter for STN 125408/127, is listed below:

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

Final Protocol Submission: June 30, 2019

Study Completion Date: August 30, 2020

Final Report Submission: February 28, 2021

We note that with this supplement you have fulfilled the pediatric study requirement for an assessment in children 2 years to <4 years of age. However, the product is not ready for approval for use in children 6 months to < 2 years of age as specified in your deferred PREA postmarketing requirement (PMR #2 as listed above).

We acknowledge your December 14, 2020 submission, STN 125408(b) (4), to your BLA which includes the final study report for study V130_10, requesting approval for persons 6 months of age and older. Upon complete review of STN 125408(b) (4) we will consider whether the PREA PMR #2 has been fulfilled.

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