Our STN: BL 125692/16

SUPPLEMENT APPROVAL
PMRs FULFILLED

Seqirus, Inc.
Attention: Kevin Darryl White
475 Green Oaks Parkway
Holly Springs, CA 27540

November 17, 2021

Dear Mr. White:

We have approved your request submitted and received on May 18, 2021, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Influenza A (H5N1) Monovalent Vaccine, Adjuvanted (AUDENZ) manufactured at your facility in Holly Springs, NC and at (b) (4) to include results from clinical trials conducted to verify and describe the clinical benefit of AUDENZ based on demonstration of the effectiveness of Flucelvax Quadrivalent in persons 6 months through 17 years of age.

We approved BLA STN 125692/0 on January 31, 2020, 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 requirements for conducting adequate and well-controlled clinical trials to verify and describe the clinical benefit attributable to this product in persons 6 months through 17 years of age under 21 CFR 601.41:

FULFILLED ACCELERATED APPROVAL REQUIRED STUDIES

1. To conduct a study (V130_12) to evaluate the efficacy, safety and immunogenicity of Flucelvax Quadrivalent compared to a non-influenza comparator vaccine in persons 4 years to <18 years of age

   Final Protocol Submission: December 13, 2018

   Study/Trial Completion: September 30, 2019

   Final Report Submission: July 31, 2020

2. To conduct a study (Study V130_10) to evaluate the safety and immunogenicity of Flucelvax Quadrivalent 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

LABELING

We hereby approve the draft content of Package Insert labeling submitted under amendment 3, dated November 10, 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 November 10, 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.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 125692, 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.

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