Our STN: BL 125297/118

**SUPPLEMENT APPROVAL**
**PMR/PMC FULFILLED**

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

January 28, 2020

Dear Ms. Charpie:

We have approved your request submitted and received April 2, 2019, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Influenza Virus Vaccine (Agriflu®) to include data from three post-approval requirement/commitment studies conducted in pediatric and adult populations.

The review of this supplement was associated with the following National Clinical Trial (NCT) numbers: NCT01867021, NCT01346592, NCT01209780.

## LABELING

We hereby approve the draft package insert labeling submitted under amendment #6, dated January 10, 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.

## 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 requirements/commitment (PMR #2 and #3 and PMC #5) identified in the November 27, 2009 approval letter for BLA STN 125297 for Influenza Virus Vaccine. The requirements/commitment addressed in this submission are as follows:

#2 (PREA-deferred PMR)
Novartis Vaccines and Diagnostics agrees to conduct Study No. V71_18, a randomized, observer-blind, non-inferiority immunogenicity and safety study with Novartis's AGRIFLU and a US-licensed trivalent inactivated Influenza Vaccine in a pediatric population from 3 years to 17 years of age.

#3 (PREA-deferred PMR)
Novartis Vaccines and Diagnostics agrees to conduct Study No. V71_20, a randomized, observer-blind, immunogenicity and safety study with Novartis's AGRIFLU and a US-licensed trivalent inactivated Influenza Vaccine in a pediatric population from 6 months to less than 3 years of age.

#5 (PMC)
Novartis Vaccines and Diagnostics agrees to conduct a non-inferiority immunogenicity study with AGRIFLU and a US-licensed trivalent inactivated seasonal influenza vaccine in a population of adults 50 years of age and older.

**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 ages 6 months to less than 3 years of age, and 3 years to 17 years of age for this application.

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

Sincerely,

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