



Our STN: BL 125408/314

## SUPPLEMENT APPROVAL

Seqirus, Inc.  
Attention: Kevin White  
50 Hampshire Street  
Suite 900,  
Cambridge, MA 02139

September 18, 2019

Dear Mr. White:

We have approved your request submitted July 17, 2019, received July 17, 2019, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Influenza Vaccine (Flucelvax<sup>®</sup>) manufactured at your Holly Springs, NC facility to amend the package insert to include information regarding the absence of egg proteins in the vaccine.

### LABELING

We hereby approve the draft package insert labeling submitted under amendment 1, dated August 12, 2019.

### 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.

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

Sincerely,

Doran 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