



**SUPPLEMENT APPROVAL  
PMR FULFILLED**

OUR STN: 125254/642

Seqirus Pty Ltd  
Attention: Kelly T. Boyle  
Biologics Consulting Group, Inc.  
1555 King Street, Suite 300  
Alexandria, VA 22314

August 31, 2017

Dear Ms. Boyle:

We have approved your request dated October 28, 2016, to supplement your Biologics License Application submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262) for Influenza Vaccine (Afluria® Quadrivalent), manufactured at your Marburg, Germany;(b) (4) ; and Parkville, Australia facilities, to extend the indication for use in persons 5 years and older.

The review of this supplement was associated with the following National Clinical Trial (NCT) number: NCT02545543.

**LABELING**

We hereby approve the draft package insert labeling and the draft carton and container labeling submitted under Amendment 13, dated July 28, 2017.

Please provide your final content of labeling in Structured Product Labeling (SPL) format and include the carton and container labels. In addition, please submit three original paper copies for carton and container final printed labeling. All final labeling should be submitted as Product Correspondence to BLA 125254 at the time of use (prior to marketing) and include implementation information on Form FDA 356h.

In addition, please submit the final content of labeling (21 CFR 601.14) in 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>.

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.

This submission fulfills your Postmarketing Requirement #1 identified in the August 26, 2016 approval letter for STN 125254/565 for Influenza Vaccine (Afluria® Quadrivalent). The requirement addressed in this submission is as follows:

#1. Deferred pediatric study under PREA, to evaluate the immunogenicity and safety of Afluria® Quadrivalent in the pediatric population 5 through 17 years of age.

## **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 5 through 17 years of age for this application.

We will include information contained in the above-referenced supplement in your biologics license application file.

Sincerely yours,

Wellington Sun, M.D.  
Director  
Division of Vaccines and  
Related Products Applications  
Office of Vaccines  
Research and Review  
Center for Biologics  
Evaluation and Research