



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Silver Spring MD 20993

Our STN: **BL 103914/5833**

**ASSIGN / APPROVAL**

Sanofi Pasteur Inc.  
Attention: Michael F. Stirr  
Discovery Drive  
Swiftwater, PA 19370

September 29, 2015

Dear Mr. Stirr:

We have received your September 15, 2015, supplement to your biologics license application for Influenza Vaccine (Fluzone<sup>®</sup>) manufactured at your Swiftwater, PA facility, to include the correct NDC number for the Fluzone Quadrivalent multi-dose vial formulation in the 2015-2016 Fluzone Quadrivalent package insert.

Your submission is in the form of a "Supplement – Changes Being Effected" as described under 21 CFR 601.12(c)(5).

This Supplement has been reviewed under STN 103914/5833 and is approved effective this date.

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

Attachment: Approved Final Draft Labeling