



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

Our STN: BL 125510/0

Seqirus, Inc.
Attention: Loksindh Ganorkar
45 Sidney Street
Cambridge, MA 02139

September 9, 2016

Dear Ms. Ganorkar:

Attached please find a revised approval letter for your biologics license application for Influenza Vaccine, Adjuvanted (Fluad). Our original approval letter inadvertently included the sentence:

“The dating period for Influenza Vaccine, Adjuvanted shall be 12 months from the date of manufacture when stored at 2°C to 8°C.”

We have corrected this sentence in the approval letter to:

“The dating period for Influenza Vaccine, Adjuvanted shall be 12 months from the date of manufacture, but not to exceed June 30th of the influenza season for which it was formulated when stored at 2°C to 8°C.”

Please retain this correspondence for your records. We regret the inconvenience this may have caused.

Sincerely,

Marion F. Gruber, Ph.D.
Director
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research