



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

SUPPLEMENT APPROVAL

Our STN: BL **125408/174**

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

August 31, 2016

Dear Ms. Ganorkar:

We have approved your request to supplement your Biologics License Application for Influenza Vaccine (Flucelvax[®]) manufactured at your Holly Springs, North Carolina facility to include the use of MDCK cell isolated candidate vaccine virus strains obtained from two supporting WHO Collaborating Centers (the Centers of Disease Control and Prevention and the Victorian Infectious Diseases Reference Laboratory) for the manufacture of monovalent bulks.

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

Sincerely yours,

Jerry P. Weir, Ph.D.
Director
Division of Viral Products
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research