



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993-0002

DATE: April 16, 2015

TO: Mayuresh Gadre, M.S.

FROM: LCDR Theodore Garnett, Ph.D.
CBER/OVRR/DVRPA

SUBJECT: BLA 125510/0 – Information request regarding the SRID Assay

PRODUCT: FLUAD 65

SPONSOR: Novartis Vaccines and Diagnostics

Review of your BLA is ongoing and we have the following request for information:

- 1) *Please provide a list of all the SRID related documents/reports present in the BLA and indicate: if they are new to the FLUAD 65 BLA or were submitted with the Agriflu submission (STN 125297).*
- 2) *Please clarify the sites that would be used for SRID testing of (b) (4) [REDACTED] final product.*

In your reply to this memo, we recommend that you restate our request and follow it with your response. Use of this format helps organize the relevant information and provides a self-contained document that facilitates future reference. If you have any questions, please contact Dr. Theodore Garnett at 301-796-2640.