

RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125510/0 Office: OVRR

Product:
Influenza Vaccine, Adjuvanted

Applicant:
Novartis Vaccines and Diagnostics, Inc.

Telecon Date/Time: 23-Jan-2015 01:46 PM Initiated by FDA? Yes

Telephone Number:

Communication Category(ies):
1. Information Request

Author: THEODORE GARNETT

Telecon Summary:
Follow up to 09-Jan-2015 IR

FDA Participants: Theodore Garnett

Non-FDA Participants: Matthew Gollwitzer

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

See e-mail correspondence below.

From: Garnett, Theodore [<mailto:Theodore.Garnett@fda.hhs.gov>]
Sent: Friday, January 23, 2015 1:46 PM
To: Gollwitzer, Matthew
Subject: RE: STN 125510/0 (FLUAD 65): Information Request

Hi Matt,

See CBER's response to your questions below. We have also tried to address the questions submitted by Jane King in her e-mail to Drs. McCormick and Joshi on January 22, 2015. Please forward this e-mail to her as well.

Testing of samples in support of this BLA will be conducted for multiple assays, including SRID. With consideration of the information relayed by Jane King on 01/22/15, we would like to request the following: At this time we would like to receive 3 lots of final container product (along with the COAs) from the 2014/15 NH season (b) (4). We understand that these lots are not formulated as per US specifications. Please note that these lots will be used to set up and evaluate the assays for testing of this new (adjuvanted) product. Testing of these lots will not fulfil the requirements of sample testing for the BLA, and we request that both monovalent lots and drug product be made available to CBER once the 2015/16 NH Influenza campaign begins. Please maintain close communication with CBER in regards to production of these lots to ensure that in-support testing can occur in a timely manner.

Don't hesitate to contact me if you have additional questions or would like to have a teleconference about these issues.

Thanks,
Ted

From: Gollwitzer, Matthew [<mailto:matthew.gollwitzer@novartis.com>]
Sent: Thursday, January 22, 2015 2:17 PM
To: Garnett, Theodore
Subject: RE: STN 125510/0 (FLUAD 65): Information Request

Hi Ted,

I wanted to let you know where we are with the attached request for sample testing. We are still working on a response, however, I have a quick question. Are the samples requested going to be tested in Dr. McCormick's and Dr. Joshi's laboratory? I am asking because I was just made aware that one of my colleagues reached out to the both of them with various questions regarding which samples and what type of samples Novartis can provide as various samples can be submitted within the April timeframe and other samples can't. Please let me know when you get a chance.

Kind Regards,

Matt