

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: 19-Jun-2015 01:43 PM Initiated by FDA? Yes

Telephone Number:

Communication Category(ies):
1. Mid-Cycle Communication

Author: KIRK PRUTZMAN

Telecon Summary:
Communication to Sponsor of the Mid-Cycle Communication Meeting Summary

FDA Participants: KIRK PRUTZMAN, BRENDA BALDWIN, THEODORE GARNETT

Non-FDA Participants: MAYURESH GADRE

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

From: Prutzman, Kirk C
Sent: Friday, June 19, 2015 1:43 PM
To: mayuresh.gadre@novartis.com
Cc: Baldwin, Brenda; Garnett, Theodore
Subject: STN 125510 - Mid-Cycle Communication Meeting Summary

Mr. Gadre,

Please find attached the meeting summary from our May 20, 2015, Mid-Cycle Communication Meeting. If you have any questions, please contact me at the information below.

Regards,

Kirk Prutzman, PhD

Primary Reviewer/Regulatory Project Manager

CBER/OVRR/DVRPA/CMC3

Food and Drug Administration

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug
Administration Silver
Spring MD 20993

Application Type and Number: BLA 125510/0

Product Name: FLUAD, Influenza Vaccine, Adjuvanted

Proposed Indication: Active immunization in persons 65 years of age and older against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine.

Applicant: Novartis Vaccines and Diagnostics, Inc.

Meeting Date & Time: May 20, 2015 11:00 AM

Subject: Mid-Cycle Communication Summary

CBER Attendees:

Brenda Baldwin, Ph.D.	Review Committee Chair
Kirk Prutzman, Ph.D.	Regulatory Project Manager
Theodore Garnett, Ph.D.	Regulatory Project Manager
Elizabeth Sutkowski, Ph.D.	Branch Chief (OVRR/DVRPA/RRB3)
Sarah Browne, M.D.	Clinical Reviewer
Wellington Sun, M.D.	Division Director (OVRR/DVRPA)
Marion Gruber, Ph.D.	Office Director (OVRR)

Contractor (PDUFA V) Attendees:

Melanie Sands	Consultant, Eastern Research Group
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Novartis Vaccines and Diagnostics, Inc. Attendees:

Gordon Byrne	Head, Regulatory Affairs
Kelly Lindert	Head, Development
Tom Crean	Associate Director, Regulatory Affairs-CMC
Sylvie Tomczyk	Head, Global Pharmacovigilance
Brett Leav	Senior Cluster Physician
Mayuresh Gadre	Senior Specialist, Regulatory Affairs

Meeting Discussion:

A list of agenda items for the Mid-Cycle Communication was provided to Novartis Vaccines and Diagnostics, Inc. (NVD) on May 19, 2015 and appears below. A summary of the discussion that occurred during the teleconference meeting held on May 20, 2015, follows each of the agenda items where appropriate (in italics):

1. Status of issues identified and their resolution

a. Information Requests

CBER discussed that they had received responses from NVD to all of the Information Requests (IR) sent prior to the May 8, 2015, Mid-Cycle Meeting. CBER indicated that they had one outstanding IR (Sent to NVD on May 15, 2015) and they had another IR forthcoming.

b. Labeling

CBER discussed that they had sent initial labeling comments on the Carton and Container labels in the May 15, 2015, IR. CBER indicated that they would be sending comments on the Package Insert label after the BLA review has progressed further.

c. Launch lots

CBER indicated that they were still waiting for NVD to submit their launch lots for testing.

CBER asked NVD when they were planning to submit their launch lots. NVD indicated that they were planning to submit launch lot samples from the 2016/2017 season to CBER in March of 2016. CBER asked NVD if they were planning to have any lots made for the 2015/2016 flu season. NVD acknowledged that they were not planning to manufacture lots for the 2015/2016 flu season. CBER asked NVD to clarify whether EU-released lots were sent to OCBQ. NVD affirmed that such lots had been submitted. CBER discussed that launch lots had been expected to be received this summer; thus, CBER asked NVD to confirm that this decision meant that NVD was seeking licensure without any launch lots. NVD agreed. CBER told NVD that they would need to get back to them on what would be required in the BLA in light of NVD's decision to not manufacture lots for the 2015/2016 flu season.

2. Status of review of safety data

CBER indicated that there was no major safety issues identified to date.

3. Risk management

CBER indicated that they were in general agreement with NVD's risk management plan. However, CBER pointed out that there were questions regarding the risk management plan contained in the May 15, 2015, IR that needed to be addressed by NVD for CBER to complete their review.

4. Miscellaneous items
 - a. Meetings update

CBER informed NVD that a VRBPAC meeting was planned for September 15-16, 2015. CBER will get back to NVD on specific dates and times of when the VRBPAC will meet to discuss FLUAD. CBER also told NVD that they will be scheduling a late-cycle communication meeting with NVD in the near future and will get back to NVD with the date and time of the meeting.

- b. Projected milestones

CBER indicated that the review milestones remain unchanged at this time.

- c. Post-marketing issues

- i. Post-marketing requirements

CBER noted that approval under the accelerated approval regulations requires that confirmatory trials be conducted in the post-marketing period to confirm the efficacy of the FLUAD vaccine in the elderly. The upcoming trial that would fulfill this commitment if successful is V118_18. CBER stated that comments concerning the trial protocol were sent to NVD on March 5, 2015, (under IND(b) (4) and asked NVD for an update on the status of the upcoming trial.

NVD indicated that their responses will be submitted within the next week.

CBER confirmed that FLUAD aQIV clinical trials V118_05 (6 months to 72 months), V118_14 (less than 6 months), and V118_19 (6 months to less than 9 years) will be or are currently being performed to satisfy the PREA requirements.

- ii. Post-marketing commitments

CBER indicated that there were no issues identified to date that might result in a post-marketing commitment.

NVD's Questions for CBER:

NVD indicated that they had submitted an amendment that contained a revised clinical study report to include the updated HAI data. CBER acknowledged receipt of the amendment.

NVD indicated that they are updating the Package Insert (PI) to include the revised HAI data and asked CBER when they should submit the updated PI to the BLA. CBER confirmed that an updated PI should be provided, and informed NVD that this request would be included in a forthcoming IR.

NVD indicated that they have generated a Periodic Safety Update Report (PSUR) for FLUAD that is being submitted to the IND as part of the annual report. NVD asked CBER if they should also submit the PSUR to the BLA. CBER agreed that NVD should submit the PSUR to the BLA.

NVD asked CBER to provide more details on the September 15-16, 2015, VRBPAC meeting. CBER indicated that VRBPAC meetings that discuss new products typically last an entire day. CBER told NVD that they should prepare a briefing document for the VRBPAC committee that is an overview of their pivotal clinical trial (typically 30 – 40 pages). NVD should expect to present their assessment of the safety and efficacy data at the meeting. CBER did not expect to have a closed VRBPAC session for this vaccine. CBER advised NVD to check the VRBPAC webpage. Also, CBER offered to provide NVD with an example of a VRBPAC meeting briefing package that NVD could use to help them prepare.

Meeting Ended.