

RECORD OF TELEPHONE CONVERSATION

Submission Information

Application Type	BLA
STN	125428/0.0
Review Office	OVRR
Applicant	Dynavax Technologies Corporation / Lic. # 1883
Product	Hepatitis B Vaccine (Recombinant), Adjuvanted
Trans-BLA Group:	No

Telecon Details

Telecon Date/Time	08-MAY-2017 11:12 AM
Author	Silvia Perezvilar
EDR	No
Post to Web	Yes
Outside Phone Number	
FDA Originated?	No
Communication Categories	IR - Information Request
Related STNs	None
Related PMCs	None
Telecon Summary	Email IR from Pharmacovigilance requesting more details on proposed PV studies
FDA Participants	Sudhakar Agnihothram, Richard Daemer, and Katherine Berkousen, RPMs, OVRR/DVRPA.
Applicant Participants	Elaine Alambra, Senior Director, Regulatory Affairs

Telecon Body:

From: Agnihothram, Sudhakar
Sent: Monday, May 08, 2017 11:12 AM
To: 'Elaine Alambra'

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Cc: Berkhausen, Katherine; Daemer, Richard J.

Subject: STN 125428 Information Request on the Propose Pharmacovigilance Plan

Dear Elaine,

Please find our request for information on the proposed Pharmacovigilance plan.

Pharmacovigilance Plan version 2.0

1. Safety data in persons with HIV infection have been identified by you as “important missing information”.

No clinical studies have been conducted to assess safety of Heplisav among individuals with HIV infection. Heplisav, if approved, is likely to be used in this sub-population. You have indicated in the PVP that “*plans for studies of Heplisav in persons with HIV infection are being developed in the post-marketing setting*” (page 40). Nonetheless, the Summary of planned Pharmacovigilance actions (page 43) only includes routine pharmacovigilance to address this “important missing information”. Routine pharmacovigilance appears by itself insufficient to resolve concerns regarding use of the vaccine in this important sub-population.

Please clarify your post-marketing plans for studies of Heplisav in persons with HIV infection.

2. Safety data in persons with chronic liver disease have been identified by you as “important missing information”.

No specific studies have been conducted to assess safety of Heplisav among individuals with chronic liver disease. Heplisav, if approved, is likely to be used in this sub-population. You have indicated in the PVP that “*plans for studies of Heplisav in persons with chronic liver disease are being developed in the post-marketing setting*” (page 40). Nonetheless, the Summary of planned Pharmacovigilance actions (page 43) only includes routine pharmacovigilance to address this “important missing information”. Routine pharmacovigilance appears by itself insufficient to resolve concerns regarding use of the vaccine in this important sub-population.

Please clarify your post-marketing plans for studies of Heplisav in persons with chronic liver disease.

3. Safety data in persons having concomitant vaccinations have been identified by you as “important missing information”.

No specific studies have been conducted to assess safety of Heplisav among individuals receiving concomitant vaccination such as influenza, pneumococcal, or herpes zoster vaccines. You have indicated in the PVP that “*plans for studies of Heplisav concomitantly administered with other vaccines are being developed in the post-marketing setting*” (page 40). Nonetheless, the Summary of planned Pharmacovigilance actions (page 43) only includes routine pharmacovigilance to address this “important missing information”.

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Please clarify your post-marketing plans for studies of Hepvisav in persons with concomitant vaccinations.

Please provide your response by 5/15/17.

Thanks so much,

Sudhakar