

Information Request Email, Study Site, September 22, 2014 - BEXSERO

- RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125546/0 Office: OVRR

Product:

Meningococcal Group B Vaccine

Applicant:

Novartis Vaccines and Diagnostics, Inc.

Telecon Date/Time: 22-Sep-2014 10:56 AM Initiated by FDA? Yes

Telephone Number:

Communication Category(ies):

1. Information Request

Author: EDWARD WOLFGANG

Telecon Summary:

IR requesting study site information for studies V72P10, V72P10E1, V72_41, V72_29, V102_03, V72P4, V72P5

FDA Participants: EDWARD WOLFGANG, KIRK PRUTZMAN

Non-FDA Participants: PATRICIA STOEHR

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

From: Wolfgang, Edward

Sent: Monday, September 22, 2014 10:56 AM

To: 'Stoehr, Patricia'

Cc: Prutzman, Kirk C

Subject: RE: IND (b)(4) Novartis Study Sites information Request

Dr. Stoehr,

Please officially submit this information as an amendment to the BLA. In the cover letter mention that the information was previously submitted via email and is now being submitted to the BLA.

Thank you,

Ed

From: Stoehr, Patricia [mailto:patricia.stoehr@novartis.com]

Sent: Thursday, September 11, 2014 2:07 PM

To: Wolfgang, Edward

Subject: RE: IND (b)(4) Novartis Study Sites information Request

Dear Ed,

After having checked carefully our IND submissions I can confirm that this information was not submitted to the IND only sent via email. Do you want me to submit it now?

Kind regards,
Patricia

Patricia Stoehr
Senior Group Manager Regulatory Affairs
Novartis Vaccines & Diagnostics
350 Massachusetts Avenue
Cambridge, MA 02139
USA

Phone: +1 617 871-8060
Fax: +1 617 871-4711
Email : patricia.stoehr@novartis.com

From: Wolfgang, Edward [mailto:Edward.Wolfgang@fda.hhs.gov]
Sent: Thursday, September 11, 2014 10:04 AM
To: Stoehr, Patricia
Cc: Wolfgang, Edward
Subject: RE: IND (b)(4) Novartis Study Sites information Request

Dr. Stoehr,

On May 15th we received the email below in response our information request that included the attached PDF. Please provide the date and IND amendment # where this table was taken.

Thank you,
Ed

From: Stoehr, Patricia [mailto:patricia.stoehr@novartis.com]
Sent: Thursday, May 15, 2014 7:15 PM
To: Wolfgang, Edward
Cc: Prutzman, Kirk C
Subject: RE: IND (b)(4) Novartis Study Sites information Request

Dear CDR Wolfgang,

Reference is made to your email below. Please find attached the requested information. I hope the provided information satisfactory answers your request. Please do not hesitate to get back to me in case of any questions you might have.

Best regards,
Patricia

Patricia Stoehr
Senior Group Manager Regulatory Affairs
Novartis Vaccines & Diagnostics
350 Massachusetts Avenue
Cambridge, MA 02139
USA

Phone: +1 617 871-8060
Fax: +1 617 871-4711
Email : patricia.stoehr@novartis.com

From: Wolfgang, Edward [mailto:Edward.Wolfgang@fda.hhs.gov]

Sent: Thursday, May 01, 2014 2:29 PM

To: Stoehr, Patricia

Cc: Prutzman, Kirk C; Wolfgang, Edward

Subject: RE: IND (b)(4) Novartis Study Sites information Request

Importance: High

Dr. Stoehr,

As was provided for study V72_41, please provide the study sites information with clinical investigator names, site numbers, and addresses for each study listed below.

Please include the numbers of subjects enrolled at each study site and any protocol deviations that occurred.

In addition, for these studies, please send the immunogenicity line listings in a readable file format. We would like these line listings as soon as possible for our review with the pre-BLA meeting materials.

Study	Phase of Clinical Investigation	Age at enrollment	Study Title	
V72P10	2b/3	11-17	Observer-blind, multi-center, randomized, controlled, safety, and immunogenicity study in healthy adolescents with various schedules	pivotal-datasets will be provided
V72P10E1	2b/3	13-19	Open-label, multi-center, extension study to assess antibody persistence at 18 months after the completion of the vaccination course in study V72P10	pivotal-datasets will be provided
V72_41	3	11-17	Observer-blind, multi-center, comparative study evaluating the safety and immunogenicity of rMenB+OMV NZ formulated with OMV manufactured at two different sites, in healthy adolescents	pivotal-datasets will be provided
V72_29	3	18-24	Observer blind, multi-center, controlled study, to evaluate the effect of rMenB+OMV NZ and MenACWY on pharyngeal carriage of <i>N. meningitidis</i> in young adults	pivotal-datasets will be provided

Study	Phase of Clinical Investigation	Age at enrollment	Study Title	
V102_03	2	11-25	Observer blind, controlled, randomized, multi-center, study of-----(b)(4)----- combination vaccination formulation in adolescents and young adults	pivotal-datasets will be provided
V72P4	2	18-50	Open-label, multi-center, safety, and immunogenicity study in healthy (at-risk) adults	supportive – NO datasets will be provided
V72P5	1	18-40	Observer blind, single-center, randomized, safety, and immunogenicity study in healthy adults	supportive – NO datasets will be provided

Thanks,
Edward Wolfgang, MSA, BSN, RAC
CDR, USPHS
Director Regulatory Review Officer
Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Vaccines
Division of Vaccines and Related Products Applications
301-796-2640

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