

From: Smith, Michael (CBER)  
To: [Devlin, Carmel \(Carmel.Devlin@pfizer.com\)](mailto:Devlin.Carmel@pfizer.com)  
Cc: [Burns, Drusilla L.](#); [Garnett, Theodore](#); [Naik, Ramachandra](#)  
Subject: STN 125549: Autoimmune cases IR  
Date: Tuesday, June 17, 2014 3:18:00 PM  
Attachments: [STN 125549 autoimmune cases IR 17JUNE14.pdf](#)

**APPROVED**

*By Michael Smith, Ph.D. at 3:54 pm, Jun 18, 2014*

Carmel,

Donna Boyce informed Marion Gruber on June 4, 2014, of 13 autoimmune cases and she also e-mailed Dr. Gruber the minutes from the May 1, and May 20, 2014, Data Monitoring Committee meeting and a PowerPoint presentation containing five slides. The review team has the attached Information Request (IR) regarding the autoimmune cases, please respond to comments 1-3 as soon as possible by submitting your answers in an amendment to the BLA. Additionally, please submit the three documents that were e-mailed to Dr. Gruber as an amendment to the BLA and reference the June 4, 2014, e-mail.

Also, please remember to consistently use "Wyeth Pharmaceuticals Inc., a subsidiary of Pfizer Inc." as the name of the applicant on the FDA form 356h (Pfizer Inc. was listed in the last rolling portion of the BLA).

Regards,

Mike

- Please confirm receipt of this IR

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**CENTER FOR BIOLOGICS EVALUATION AND RESEARCH  
OFFICE OF VACCINES RESEARCH AND REVIEW  
DIVISION OF VACCINES AND RELATED PRODUCT APPLICATIONS**

**Date:** June 17, 2014

**Pages:** 2

**To:** Carmel Devlin  
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**STN#:** 125549/0

**Product:** Meningococcal Group B Vaccine

**Subject:** CBER request for additional information regarding Donna Boyce's June 4, 2014, e-mail to Marion Gruber that contained the following: Data Monitoring Committee (DMC) minutes from meetings that occurred on May 1, and May 20, 2014, and a PowerPoint presentation entitled "rLP2086 Autoimmune Case Discussion, Cases included in June 2014 BLA".

1. With regard to the information provided (summaries of DMC meeting held on May 1st and May 20th, sponsor slide presentation), we note that cases of multiple sclerosis and alopecia were reviewed by the DMC, but not listed among the 13 subjects identified with an autoimmune condition. Please submit, as an amendment(s) to the BLA, narratives for the cases of multiple sclerosis and alopecia and the information presented at the DMC meeting held May 20th.
2. Please provide the following as an amendment(s) to the BLA:
  - a. A case narrative for the subject with worsening gluten intolerance or provide the study B1971003 report page number(s) where the narrative can be located
  - b. Study B1971003: Summary of protocol changes
  - c. Study B1971004: We note on page 51 of 537 of the study report body that some of the adverse events were summarized, but an accompanying listing of all adverse events was not provided. Please provide a listing of adverse events categorized according to MedDRA terms.
3. Please provide the following as an amendment(s) to the IND:
  - a. Data listings and summaries for study B1971005 stage 2 (please provide in a format similar to the information that was provided to the DMC)
  - b. Any new cases of subjects with an autoimmune or neuroinflammatory disorder from studies B1971009, -1014, -1015 or -1016 that are identified during the BLA review period
4. We note (DMC meeting held May 1<sup>st</sup>) the DMC's recommendation to assess background rates for the autoimmune conditions identified to date. Please provide estimates of background rates for each autoimmune condition, including alopecia and multiple sclerosis, using information from databases that are as comparable as possible to your study population. A BLA amendment containing this information can be separate from the written responses for the preceding three comments.

In your reply to this information request, we recommend that you restate the item and follow it with your explanation or clarification. 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 LCDR Mike Smith, Ph.D., at 301-796-2640.