DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

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

Date: **May 10, 2017**

Pages: **3**

To: **Jody Gould, Ph.D.**
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From: **Division of Vaccines and Related Products Applications**
Office of Vaccines Research and Review
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STN: **125614/0**

Product: **Shingrix (Zoster Vaccine Recombinant, Adjuvanted)**

Subject: **May 8, 2017, CBER-GSK teleconference/Follow-up advice**

Dear Dr. Gould,

As we discussed during the May 8, 2017, teleconference, we are providing below details regarding the required tables and additional information:

1. Please find attached post-text demography tables from the Zoster-006 and Zoster-022 Clinical Study Reports (CSRs) that do not require revision. (Yellow highlight = No)

2. Please provide the numbers and proportions of subjects in the TVC of the main pooling for each vaccination group for the following safety outcomes by gender, ethnicity and race for the protocol pre-specified age groups (50 – 59, 60 – 69 and ≥ 70):
    - Reporting at least one unsolicited adverse events (AEs) during the 30 day post-vaccination period
    - Reporting at least one Grade 3 non-serious unsolicited AE during the 30 day post vaccination period
    - Reporting the occurrence of unsolicited AEs with a medically attended visit during M0 – M8
    - Reporting at least one SAE during the 30 day post-vaccination period
    - Reporting at least one SAE during M0 – M14
    - Reporting at least one pIMD during the whole post-vaccination period
    - Reporting at least one pIMD during M0 – M14
    - Who died within the 30 day post-vaccination periods
    - Who died during M0 – M14
    - Who died during the whole post-vaccination period

    For solicited events on the diary card subset during the solicited AE collection period, please provide the following by gender, race and ethnicity by the age groups specified above:
    - N(%) of subjects with at least one solicited event, one local solicited AE, one general solicited AE overall and by Dose 1 and Dose 2
    - N(%) of subjects with at least one Grade 3 solicited AE, one Grade 3 solicited local AE, one Grade 3 solicited general AE overall and by Dose 1 and Dose 2
    - N(%) of subjects reporting each specific solicited event (any Grade and Grade 3) solicited event by Dose 1 and Dose 2

    As discussed in the May 8, 2017, telecon, please provide these tabulations as a separate report.

3. Please provide the following analyses on VE:
    - Zoster-006: Subgroup analyses of HZ VE by gender, race, ethnicity, and region using the modified Total Vaccinated Cohort for the Final HZ efficacy analysis step.
    - Zoster-006: Subgroup analyses of HZ VE by race and ethnicity using the modified Total Vaccinated Cohort for the End of Study analysis step.
    - Zoster-022: Subgroup analyses of HZ VE by race and ethnicity using the modified Total Vaccinated Cohort.
    - Pooled Zoster-006/022- Subgroup analyses of HZ VE in subjects >= 70 YOA by race and ethnicity using the modified Total Vaccinated Cohort.
    - Pooled Zoster 006/022: Subgroup analyses of PHN VE in subjects >=70 YOA by gender, race, region and ethnicity using the modified Total Vaccinated Cohort.

For the above requested subgroup VE analyses, please provide the results by the pre-specified age stratum and overall.

4. According to the protocols, subjects who suspected they had a case of HZ were to complete a "Suspected HZ Rash" diary card to return to the study site. Please provide the number and proportions of subjects in the TVC of each vaccination group in both Zoster-006 and Zoster-022 who suspected they had a case of HZ and completed a "Suspected HZ rash" diary card, and the numbers and proportions of subjects in each vaccination group who were determined by the investigator to have a rash that was NOT a clinically diagnosed suspected case of HZ.

If you have any questions about this communication, please contact Ramachandra Naik, Ph.D. or Michael Smith, Ph.D. at (301) 796-2640.