Hi Dana,

Checking in to see if you have received our two information requests, see below.

Likewise, we need to know exactly what you are cross-referencing from the penatcel file. You state you are cross-referencing STN 125145/0. But surely there has been approved modifications to the cmc in this file that are beyond the original BLA application. Therefore, unless you are ONLY cross-referencing 125145/0, we need nothing else. But if you plan on using other approved supplements to STN 125145 we will need to know the exact ones.

Please contact me at as soon as possible, our decision to file is this Friday, and this information and any outstanding CR letters under STN 125145 that will affect our filling decision.

Thanks,

juan

From: Lacayo, Juan
Sent: Tuesday, May 13, 2014 3:47 PM
To: 'dana.harrison@sanofipasteur.com'
Subject: STN 125525

Hi Dana,

I was hoping you could answer a potentially complicated question.

With regard to STN 125525. There are a number of outstanding CR letters under STN125145. Could you please tell me what, if any , of these CR letters will have any impact on the quadracel application.

Specifically, I am concerned with STN 125145 supplements 269, (b) (4), 293, and (b) (4).

Thanks,

juan

and

Mon 5/12/2014 3:28 PM

Dear Dana Harrison:

We are reviewing your Biologics License Application (BLA) dated March 24, 2014, for Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine and have determined that the following information is necessary to take complete action. Please promptly submit your written response to the following items so that we may continue evaluating your BLA:

1. Please provide data to support the stability of the performance of the immunoassays used to assess responses to diphtheria, tetanus and pertussis from the time of validation to the analysis of samples in in study M5I02.

2. If you retested samples in your immunologic assays and replaced specific data points in study M5I02, please provide a summary of retesting either as part of the Clinical Study Report or separately. In this summary, we request you include a listing of the values replaced during data cleaning, reasons for sample retesting, and an assessment of the impact of the retesting and replacement of values.

3. Please provide the transfer protocols and reports for the anti-diphtheria and anti-tetanus assays described in Table 1 of Appendix 11 (Assay Techniques

and Standard References) in Section 5.3.5.1, Inter Laboratory Standardisation Methods Quality Assurance.

If you have any questions, please contact the Regulatory Project Manager, Juan Lacayo, Ph.D., at (301) 796-2640.

Juan C. Lacayo, Ph.D.
LCDR, United States Public Health Service
Regulatory Reviewer/Project Manager
CMC Review Branch 1
Division of Vaccines and Related Product & Applications
Office of Vaccines Research & Review
Center for Biologics Evaluation & Research
U.S. Food and Drug Administration
WOC2 2329 HFM-481
1401 Rockville Pike
Rockville, MD 20852
Tel: 301-796-2640