Information Request Email, June 6, 2014 - GARDASIL 9

RECORD OF EMAIL COMMUNICATION
Submission Type: BLA Submission ID: 125508/0 Office: OVRR
Product: Human Papillomavirus 9-valent Vaccine, Recombinant
Applicant: Merck Sharp & Dohme Corp.
Telecon Date/Time: 06-Jun-2014 12:13 PM
Initiated by FDA? Yes
Telephone Number: N/A (email)
Communication Category: Information Request
Author: Laura Montauge
Telecon Summary: Feedback regarding LRP templates submitted in 125508/0.2
FDA Participants: Laura Montague, Bharat Khurana
Non-FDA Participants: Alison Fisher, David Gutsch, William Rankin
Trans-BLA Group: No
Related STNs: None
Related PMCs: None
Telecon Body:

From: Montague, Laura
Sent: Friday, June 06, 2014 12:13 PM
To: alison_fisher@merck.com; Rankin, _William M. (RAS-B) (william_rankin@merck.com)
Cc: Khurana, Bharat; Gutsch, David (david_gutsch@merck.com)
Subject: STN 125508; IR #12
Dear Alison and Bill,
CBER has reviewed the lot release protocols submitted in amendment 125508/0.2 on 19-Feb-2014. We have the following comments.

Comments on Attachment 1: V503 Final Container Draft Protocol

1. On page 2, please indicate the STN the bulks were released under if not 125508.
2. On page 3, please add the date of the last B&F test performed on the product to the sterility test information. An example with this included is in the attachment to this email.
3. On page 3, the reference to 21 CFR 610.12 should instead be to --(b)(4)--.
4. On page 3, remove the test for ----------(b)(4)----------, as CBER agrees with this being removed as a release test.
5. On pages 4 and 5, ----------(b)(4)---------- assay, please include the Positive control lot number and result for each type.
6. On page 6, in the (b)(4) template please include the intercept value from the standard curve.

Comments on Attachment 2 (Quadrivalent (b)(4) Type Draft Protocol) and 3 (New HPV Type (b)(4) Draft Protocol):

7. Please remove or change anything in the lot release protocol template that has been agreed to with CBER. Examples of items already agreed to:
   a. On page 3, testing the ----------(b)(4)---------- may be removed.
   b. On page 6 of attachment 3, ----------(b)(4)---------- testing maybe removed.
8. On page 6, please add the date of the last (b)(4) test performed on the product to the ---(b)(4)-- test information. An example with this included is in the attachment to this email.
9. On page 6, please submit the full (b)(4) template for each --(b)(4)--. There is a template for the (b)(4) test attached. Please indicate the test method. Based on the submission, this should be ---------(b)(4)----------.
10. On page 6 of each bulk lot release protocol, in the (b)(4) result table please add the Positive control lot number and result.

General Comments on all of the lot release protocols

11. On page 1 of all of the protocols, except those that will come in under STN 125126, please remove the reference to electronic protocols. Initially, 125508 protocols will be submitted on paper. Joe Quander will notify Merck when those protocols can be submitted electronically.
12. Please add specifications to the template once they have been agreed upon with CBER.
13. Please note that the review of this BLA is ongoing, and changes may be requested as a result of the review.

Additional comments regarding the shipment of your samples:

14. Merck indicated in William Rankin's e-mail dated February 05, 2014 that in-date Final Container Samples would be available to ship by the end of September, 2014. Please confirm that this is still the expected date.
15. CBER's sample custodian and testing labs will be moving in the late summer or early fall of 2014, and the exact date is not yet confirmed. There will be a two week pause in the receipt of samples around the time of the move. Therefore, please contact CBER prior to sending samples to the sample custodian to ensure our ability to receive them and that you are sending them to the correct address.

Please note that there are two example templates in the attachment to this email.

Thank you,

Laura
Laura Montague
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FDA/OMPT/CBER/OVRR
Division of Vaccines and Related Products Applications
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Attachment included in email:
(see next page)