Information Request Email, July 24, 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: 24-Jul-2014 11:54 AM
Initiated by FDA? Yes
Telephone Number: N/A (email)
Communication Categories: Advice and Information Request
Author: Laura Montague
Telecon Summary: IR #15 - LRP feedback and request that Merck submit updated LRP templates by 9-5-2014
FDA Participants: Laura Montague, Bharat Khurana
Non-FDA Participants: Alison Fisher
Trans-BLA Group: No
Related STNs: None
Related PMCs: None
Telecon Body:
From: Montague, Laura [mailto:Laura.Montague@fda.hhs.gov]
Sent: Thursday, July 24, 2014 11:54 AM
To: Fisher, Alison L
Cc: Khurana, Bharat
Subject: STN 125508/0; Information Request #15
Dear Alison,
Thank you for the responses to CBER's Information request #12, which were submitted in amendment 23 of STN 125508 on July 2, 2014. CBER has reviewed the amendment, and has the following comments regarding the lot release protocols for 125508:
Comments:

1. Merck agreed to add the STN (125126) next to the HPV bulks for Types 6, 11, 16 and 18.
2. On page 3, CBER had requested the last (b)(4) test date be included. CBER agrees with Merck's request that this additional --(b)(4)---- reporting information not be a requirement for batch release.
3. Merck agreed to change the reference to (b)(4).
4. Merck agreed to remove the test for ----------(b)(4)----------.
5. On pages 4 and 5 CBER had requested positive control lot information be included in the template. Merck has requested to maintain the current formatting as provided in the draft lot release protocols. CBER agrees that Merck may maintain the current formatting without the addition of this information.

6. On page 6 CBER had requested the intercept value from the standard curve be included in the (b)(4) template. Merck has requested to maintain the current format. CBER agrees that the current format may be maintained.
7. On the (b)(4) draft lot release protocols, CBER had requested that Merck remove or change anything in the lot release protocol template that had been agreed to with CBER. Changes already agreed to were:
   a. On page 3, testing the ----------(b)(4)---------- may be removed.
   b. On page 6 of attachment 3, ----------(b)(4)---------- testing may be removed. Merck agreed to make these changes.
8. CBER agrees, as above in comment 2, that the template for sterility may be maintained as submitted.
9. CBER agrees that, for (b)(4) lot release protocols, the full (b)(4) template as submitted for the final container does not need to be used. The (b)(4) assay reporting format as described in the initially-proposed lot release protocols is sufficient and acceptable.
10. CBER agrees, as described above in comment 5, to allow Merck to maintain the template for the (b)(4) result table.
11. Merck agreed to remove the reference to electronic protocols from 125508 lot release protocol templates until Joe Quander has notified Merck that they may be sent electronically.
12. Merck agreed to add the specification to the templates once they have been agreed to with CBER.

Request and Advice:
(a) CBER requests that Merck submit updated lot release protocol templates for STN 125508 final container and bulks to the BLA once the agreed-upon corrections have been made. The templates should be submitted to the BLA by September 5, 2014.
(b) CBER's Sample Custodian will ***not*** receive lot release samples between Monday, August 1, 2014 and Friday, August 15, 2014. Samples sent after August 15, 2014 should use the new address for the White Oak Campus.
Thank you,
Laura

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