

From: Krissy.Carrington@sanofipasteur.com
To: [Hoffman, Kelsy](#)
Cc: [Rivers, Katie](#)
Subject: RE: Information Request for BLA125563/0
Date: Friday, October 10, 2014 4:57:57 PM

Thank you very much for the quick response and clarification. Kind regards,
Krissy

From: Hoffman, Kelsy [mailto:Kelsy.Hoffman@fda.hhs.gov]
Sent: Friday, October 10, 2014 4:25 PM
To: Carrington, Krissy (sanofi pasteur)
Cc: Rivers, Katie
Subject: RE: Information Request for BLA125563/0

Krissy,

CBER's comment is referring to the three facilities that manufacture the product and MCM Vaccine Company. Please clarify if the MCM Vaccine company is the license holder and uses the three facilities (Sanofi Pasteur Limited, Sanofi Pasteur, and Merck) as contract manufacturers. If not, please describe the manufacturing relationship between all four companies (MCM, Sanofi Pasteur Limited, Sanofi Pasteur, and Merck).

It is acceptable to send the IR response via email by October 17, 2014, along with ESG submission the following week.

Please let me know if you have any further questions.

Thanks,
Kelsy

Kelsy F. Hoffman, Ph.D.
Regulatory Reviewer/Project Manager
FDA/CBER/OVRR/DVRPA
10903 New Hampshire Ave.
WO71-3205
Silver Spring, MD 20993-0002
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From: Krissy.Carrington@sanofipasteur.com [<mailto:Krissy.Carrington@sanofipasteur.com>]
Sent: Friday, October 10, 2014 4:00 PM
To: Rivers, Katie

Cc: Hoffman, Kelsy
Subject: RE: Information Request for BLA125563/0

Dear Katie,

This e-mail is a request to seek clarification regarding Question. 1. The question listed three manufacturing facilities:

- Sanofi Pasteur Limited Ontario, Canada (FEI: 3002888623)
- Sanofi Pasteur (b) (4)
- Merck Sharp & Dohme Corp. (b) (4)

However, CBER also referred to the following:

The relationship is referred to as a “partnership”, “co-developers”, or “joint collaboration.” Please indicate if the **three facilities** listed above are considered contract manufactures to MCM Vaccine Co. or if the manufacturing is considered either a shared manufacturing or divided manufacturing paradigm **between the four facilities**.

Could you clarify what four facilities CBER is referring to? Thank you.

I would also like to have your permission to send the IR response via e-mail by the 17th October 2014 due date followed by the ESG submission the following week. Thank you for your approval of this proposal. Kind regards,
Krissy

From: Rivers, Katie [<mailto:Katie.Rivers@fda.hhs.gov>]
Sent: Friday, October 03, 2014 10:25 AM
To: Carrington, Krissy (sanofi pasteur)
Cc: Hoffman, Kelsy
Subject: Information Request for BLA125563/0

Dear Ms. Carrington,

We have the following information request (IR) for your BLA, STN125563/0:

1. There is no clear description in your BLA application as to the exact working relationship between MCM Vaccine Company and the following facilities:
 - Sanofi Pasteur Limited Ontario, Canada (FEI: 3002888623)
 - Sanofi Pasteur (b) (4)
 - Merck Sharp & Dohme Corp. (b) (4)

The relationship is referred to as a “partnership”, “co-developers”, or “joint collaboration.” Please indicate if the three facilities listed above are considered contract manufactures to MCM Vaccine Company or if the manufacturing is considered either a shared manufacturing or divided manufacturing paradigm between the four facilities.

2. Please provide the following information:
 - a. A detailed description of how MCM Vaccine Company will ensure that the

manufacture of the drug substance and drug product complies with the applicable provisions of the BLA and the applicable regulations since the license holder has the ultimate responsibility of ensuring compliance.

- b. A detailed description of how communications between the three facilities and MCM Vaccine Company will occur in instances such as manufacturing deviations and investigations.
- c. A list of all standard operating procedures applicable to the working arrangement between the four facilities, as applicable.

Please reply to this IR by Friday, October 17, 2014. Please let me know if you have any questions.

Thank you,
Katie

Katie H. Rivers, M.S.
Regulatory Project Manager, RRB1
FDA/CBER/OVRR/DVRPA
10903 New Hampshire Ave., HFM-481
Silver Spring, MD 20993-0002

Phone 301-796-2640
Fax 301-595-1244

Please note that our mailing address for regulatory submissions has changed, the new mailing address is:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave
WO71-G112
Silver Spring, MD 20993-002

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