

From: Ananyeva, Natalya
Sent: Wednesday, April 11, 2012 3:23 PM
To: Tilghman, Tracy
Cc: Shields, Mark; Kirschbaum, Nancy; Lee, Timothy; Lindsey, Kimberly; Melhem, Randa
Subject: RE: Resubmission Acknowledgement for STN 125392 - Please respond by COB 10-Apr-12

Dear Tracy,

Summarizing the responses from all review committee members, the resubmission STN 125392/0.11 can be considered as a Complete Response to the CR letter dated 19 September 2011.

Omrix/Ethicon formally addressed all CR items. Additional information to evaluate the adequacy of the responses will be collected via an Information Request mechanism.

Re-submission is classified as a Class 2 re-submission as it contains a large body of new clinical data and the Applicant's corrective actions to address the issues from the Pre-License Inspection.

Please prepare an Acknowledgement letter.

Regarding a CDRH consult for the matrix component of the Fibrin Pad: Roxolana Horbowyj from CDRH will continue working with Kimberly.

I will define whether or not an additional CDRH consult is needed during the review of the re-submission.

Thank you.
Natalya

From: Barash, Faith
Sent: Friday, April 06, 2012 1:44 PM
To: Tilghman, Tracy
Cc: Ananyeva, Natalya; Shields, Mark
Subject: RE: Resubmission Acknowledgement for STN 125392 - Please respond by COB 10-Apr-12

Hi Tracy,

1. Yes, this submission is sufficient to be considered a complete response.
2. Yes, this can be considered a Class 2 resubmission.

Please remember that I am the OBE reviewer for the Pharmacovigilance planning, not the clinical reviewer.

Thanks
Faith

From: Scott, John
Sent: Friday, April 06, 2012 1:35 PM
To: Tilghman, Tracy
Cc: Ananyeva, Natalya; Shields, Mark; Lindsey, Kimberly
Subject: RE: Resubmission Acknowledgement for STN 125392 - Please respond by COB 10-Apr-12

Hi Tracy,

None of the CR issues were statistical, so I'll defer entirely to Kimberly and Natalya on the sufficiency and Class.

Thanks,
John

From: Brown, La'Nissa
Sent: Monday, April 09, 2012 4:27 PM
To: Tilghman, Tracy
Cc: Shields, Mark; Mahmood, Iftekhar; Lindsey, Kimberly; Ananyeva, Natalya
Subject: STN BLA 125392/11 Complete Response to CR letter
Hello All,

1. Please indicate whether this submission is sufficient to be considered a Complete Response and to warrant the restart of the review clock.

The complete response in STN BLA 125392/11 is sufficient for review from the Pharmacology/Toxicology reviewer perspective.

2. Please provide your assessment of the Class of the resubmission.

I will defer class designation to the Scientific Lead with consultation from the Medical Officer since there is substantial clinical data.

Thanks,
La'Nissa A. Brown-Baker, Ph.D.
Pharmacologist
Division of Hematology HFM-392
Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Blood Research and Review
1401 Rockville Pike
Rockville, MD 20852
(301)827-3897 Office (301)827-3533 Facsimile
la'nissa.brown-baker@fda.hhs.gov

From: Cato, Dennis
Sent: Friday, April 06, 2012 3:24 PM
To: Tilghman, Tracy
Cc: Ananyeva, Natalya; Shields, Mark; 'Pat Holobaugh'
Subject: RE: Resubmission Acknowledgement for STN 125392 - Please respond by COB 10-Apr-12

Hello Tracy,

As per our telephone conversation on Friday April 6, 2012, the following applies:

The information you request is outside the expertise of the BIMO group and may be best addressed to the committee. In addition, as stated in the Sponsor's response to the CR letter, all outstanding inspectional issues identified during the BIMO inspections at the clinical sites were adequately addressed by the relevant Clinical Investigator for the sites inspected.

Because of PDUFA review timeframes and the fact that the newly submitted studies were completed at 10 centers overseas, a decision to conduct BIMO inspections of any of these studies may present some challenges and should be made with input from the Committee Chair,

the Clinical Reviewer, and BIMO. Thanks and I hope this helps.

Dennis
301-827-2588

From: Horbowyj, Roxolana
Sent: Monday, April 09, 2012 12:35 PM
To: Lindsey, Kimberly; Tilghman, Tracy; Jain, Nisha
Cc: Ananyeva, Natalya; Shields, Mark
Subject: RE: Resubmission Acknowledgement for STN 125392 - Please respond by COB 10-Apr-12

Thank you Kimberly - agree.

From: Lindsey, Kimberly
Sent: Monday, April 09, 2012 12:28 PM
To: Tilghman, Tracy; Jain, Nisha
Cc: Ananyeva, Natalya; Shields, Mark
Subject: RE: Resubmission Acknowledgement for STN 125392 - Please respond by COB 10-Apr-12

Tracy,
Natalya, is the chair and I will defer to her to respond to the general questions once she seeks input from all review disciplines.

As for the clinical:

1. Does this resubmission warrant an Advisory Committee review? If so, please list pertinent advisory committee information or provide justification otherwise.
I do not anticipate that an advisory committee review will be necessary.

2. Does this resubmission warrant PREA?
This submission does trigger a PREA review.

3. Do you continue to require a CDRH consult or like to keep the current CDRH consult on this file? If so, please let me know. A consult request was previously generated that can be modified for the resubmission.
Please retain the current CDRH consultants for continuity. I can assist preparing in the consult request for Roxi Horbowyj.

Kimberly

From: Melhem, Randa
Sent: Wednesday, April 11, 2012 2:19 PM
To: Tilghman, Tracy; Waites, Nancy
Cc: Ananyeva, Natalya; Shields, Mark
Subject: RE: Resubmission Acknowledgement for STN 125392 - Please respond by COB 10-Apr-12

Randa

Tel: 301-827-6999

From: Tilghman, Tracy
Sent: Friday, April 06, 2012 1:28 PM
To: Melhem, Randa; Waites, Nancy
Cc: Ananyeva, Natalya; Shields, Mark
Subject: FW: Resubmission Acknowledgement for STN 125392 - Please respond by COB 10-Apr-12
Importance: High

Hello Randa and Nancy,

We have received the response to the CR letter for STN#125392 dated 19 September 2011. Currently this is being considered a Class 2 resubmission, which can potentially restart the clock and PDUFA deadlines for this submission. At this time, please provide the following information:

1. Please indicate whether this submission is sufficient to be considered a Complete Response and to warrant the restart of the review clock.

They addressed every question in the CR letter.

2. Please provide your assessment of the Class of the resubmission.

Additionally, please provide a response to the following:

DMPO

1. Does this resubmission warrant a re-inspection of the facilities? **No.**

From: Tilghman, Tracy
Sent: Friday, April 06, 2012 1:25 PM
To: Hudson, Peter; Kirschbaum, Nancy
Cc: Ananyeva, Natalya; Shields, Mark
Subject: Resubmission Acknowledgement for STN 125392 - Please respond by COB 10-Apr-12
Importance: High

Hello Peter and Nancy,

We have received the response to the CR letter for STN#125392 dated 19 September 2011. Currently this is being considered a Class 2 resubmission, which can potentially restart the clock and PDUFA deadlines for this submission. At this time, please provide the following information:

1. Please indicate whether this submission is sufficient to be considered a Complete Response and to warrant the restart of the review clock.
2. Please provide your assessment of the Class of the resubmission.

Additionally, please provide a response to the following:

CMC

1. Do you continue to require a CDRH consult or like to keep the current CDRH consult on this file? If so, please let me know. A consult request was previously generated and can be modified for this resubmission.

Please note that the review of the response to the CR letter is on a time clock. Please submit your response to me **via email by close of business on Tuesday, April 10, 2012.** If you foresee any difficulty with adhering to this deadline, please let me know at your earliest possible convenience.

The links to the pertinent SOPP and access to the resubmission are provided below:

SOPP link:

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/ucm073490.htm>

Access to resubmission:

This is an eCTD submission. Select the link to access the .enx file:

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STN#: 125392

Product: Fibrin Pad

Short Summary: Fibrin Pad is as an adjunct to hemostasis for soft tissue bleeding during retroperitoneal, intra-abdominal, pelvic, and (non-cardiac) thoracic surgery when control of bleeding by standard surgical methods of hemostasis is ineffective or impractical

Thanks,

Tracy Tilghman, MPH

Lieutenant, United States Public Health Service

Regulatory Project Manager

U.S. Food & Drug Administration

CBER/OBRR/DBA/RPMB

WOC1, RM 556N, HFM-380

Rockville, MD 20852

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