

Rana, Pratibha

From: Kennedy, Michael
Sent: Thursday, November 03, 2011 2:22 PM
To: Rana, Pratibha
Cc: Scott, Dorothy; Zhong, Lilin
Subject: RE: Second Request: STN 125389/0.13 Response to CR letter has arrived

Pratibha,

The amendment consists of a complete response and it is a Class 2 resubmission.

Thanks,

Michael C. Kennedy PhD
Laboratory of Plasma Derivatives
Division of Hematology
Office of Blood Research and Review
Center for Biologics Evaluation and Research

From: Rana, Pratibha
Sent: Thursday, November 03, 2011 11:01 AM
To: Kennedy, Michael
Subject: RE: Second Request: STN 125389/0.13 Response to CR letter has arrived

Michael,

The timeline for Class 1 is two months and for Class 2 is Six months.

As per the guidance to Industry: Classifying Resubmission in Response to Action letters:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079303.pdf>

Pratibha

From: Kennedy, Michael
Sent: Thursday, November 03, 2011 10:35 AM
To: Rana, Pratibha
Subject: RE: Second Request: STN 125389/0.13 Response to CR letter has arrived

Pratibha,

What are the review timelines for Class 1 and Class 2?

Michael C. Kennedy PhD
Laboratory of Plasma Derivatives
Division of Hematology
Office of Blood Research and Review
Center for Biologics Evaluation and Research

From: Rana, Pratibha
Sent: Thursday, November 03, 2011 10:23 AM
To: Kennedy, Michael
Cc: Scott, Dorothy; Boxenbaum, Harold; Frazier, Douglas; Frost, Mitchell M; Kim, Jessica; Olin, Rebecca; Ortega, Lillian; Popat, Alpita; Virata, Maria Luisa; Zhang, Pei; Zhong, Lilin; Zinderman, Craig E; Valencia, Iliana

Subject: Second Request: STN 125389/0.13 Response to CR letter has arrived

Michael,

Please confirm the following so we can start the review clock. If not we have to let the sponsor know that the submission is incomplete and the review clock cannot be restarted. Please let me know by COB tomorrow (Friday November 4, 2011).

1. Please confirm that the amendment is a complete response
2. And if the amendment is a Class 1 or Class 2 response.

I have attached the link to Sopp 8405.1 *Procedures for Resubmissions of an Application or Supplement for a Product Covered by PDUFA*

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

Thank you.
Pratibha

From: Rana, Pratibha
Sent: Wednesday, October 26, 2011 2:26 PM
To: Kennedy, Michael
Cc: Scott, Dorothy; Boxenbaum, Harold; Frazier, Douglas; Frost, Mitchell M; Kim, Jessica; Olin, Rebecca; Ortega, Lillian; Popat, Alpita; Virata, Maria Luisa; Zhang, Pei; Zhong, Lilin; Zinderman, Craig E; Valencia, Iliana
Subject: RE: STN 125389/0.13 Response to CR letter has arrived

Michael,

1. Please confirm that the amendment is a complete response
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<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/ucm073490.htm>

Thank you.
Pratibha

From: Rana, Pratibha
Sent: Wednesday, October 26, 2011 1:55 PM
To: Kennedy, Michael
Cc: Scott, Dorothy; Boxenbaum, Harold; Frazier, Douglas; Frost, Mitchell M; Kim, Jessica; Olin, Rebecca; Ortega, Lillian; Popat, Alpita; Virata, Maria Luisa; Zhang, Pei; Zhong, Lilin; Zinderman, Craig E; Valencia, Iliana
Subject: STN 125389/0.13 Response to CR letter has arrived
Importance: High

Michael,

The sponsor (Biotest) has responded to the Complete Response letter for this original BLA. Please have a look/review and let me know if this amendment qualifies as a complete response.

Thank you.
Pratibha

-----Original Message-----

From: CBER OBRR_eLoad_DBA
Sent: Wednesday, October 26, 2011 1:19 PM
To: Rana, Pratibha
Subject: FW: DCC Login ID 521738 loaded by DCC - DO NOT REPLY

Pratibha, this amendment from BIOTEST has been viewed and deemed as navigable, and its now accessible by using the link below.

-----Original Message-----

From: cbersecure@fda.hhs.gov [<mailto:cbersecure@fda.hhs.gov>]
Sent: Wednesday, October 26, 2011 12:33 PM
To: CBER OBRR_eLoad_DBA
Cc: OIT-CBER EDR; OIT-CBER EDR; Fauntleroy, Michael; CBER DCC EDR
Subject: DCC Login ID 521738 loaded by DCC - DO NOT REPLY

This BLA Product Correspondence DCC Login ID 521738 is now available in the EDR.

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

(b)(4)

DESCRIPTION:

Applicant: BIOTEST PHARMACEUTICALS CORPORATION / 1792

Product: IMMUNE GLOBULIN INTRAVENOUS (HUMAN)

Indication: Primary Immune Deficiency Disorders (PIDD)

Proprietary Name: BIVIGAM

APPLICATION INFORMATION:

Application Number: 125389\

eCTD Sequence Number: 0013

CBER Receipt Date: 26-Oct-2011

If you need additional assistance with this submission, please contact
ERIC Help Desk at 301-827-ERIC (3742).

PLEASE DO NOT REPLY TO THIS EMAIL. This is an automatically generated message.

Technical information for administrators - Process Track ID: 22653