

Rana, Pratibha

From: Kennedy, Michael
Sent: Thursday, November 08, 2012 8:05 AM
To: Rana, Pratibha
Subject: RE: 125389\0\47

Pratibha,

Go ahead and send the acknowledgement letter - should be a 2 month review cycle

Thanks,

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

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

From: Rana, Pratibha
Sent: Wednesday, November 07, 2012 3:40 PM
To: Kennedy, Michael; Zhang, Pei; Zhong, Lilin; Sullivan, Destry; Ovanesov, Mikhail V.
Subject: 125389\0\47

From the Sponsor for Bivigam.
Pratibha

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

From: cbersecure@fda.hhs.gov [mailto:cbersecure@fda.hhs.gov]
Sent: Wednesday, November 07, 2012 3:17 PM
To: CBER OBRR_eLoad_DBA; Rana, Pratibha
Cc: CBER IT EDR; CBER IT EDR; Fauntleroy, Michael; CBER DCC EDR
Subject: DCC Login ID 547051 loaded by DCC - DO NOT REPLY

This BLA Amendment DCC Login ID 547051 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\0\47

eCTD Sequence Number: 0044

CBER Receipt Date: 07-Nov-2012

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

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