

From: [Jones, Cecily](#)
To: [Kumar, Vasantha](#)
Subject: FW: Compliance Check for Original BLA STN 125653/0
Date: Wednesday, September 27, 2017 12:01:08 PM
Importance: High

FYI.

From: CBER Compliheck
Sent: Wednesday, September 27, 2017 11:58 AM
To: Jones, Cecily <Cecily.Jones@fda.hhs.gov>; CBER Compliheck <complheck@fda.hhs.gov>
Cc: Sausville, Robert <Robert.Sausville@fda.hhs.gov>; Anderson, Maria (CBER) <Maria.Anderson@fda.hhs.gov>
Subject: RE: Compliance Check for Original BLA STN 125653/0
Importance: High

Applicant Name: Roche Molecular Systems, Inc.
License Number: 1636

Applicant Address: Roche Molecular Systems, Inc.
4300 Hacienda Drive
P.O. Box 9002
Pleasanton, CA 94588-0900
FEI: 3004141078

Firm: Roche Molecular Systems, Inc.
(b) (4)

STN: 125653/0

Short Summary: cobas[®] Zika is a qualitative test that is run on the cobas[®] 6800 System and cobas[®] 8800 System. cobas[®] Zika enables the simultaneous detection of Zika RNA and the internal control in a single test of an infected, individual donation.

There are no ongoing or pending investigations or compliance actions with respect to the above facilities or its product(s). Therefore, the Office of Compliance and Biologics Quality, Division of Case Management does not object to the approval of this application.

Shannon Aldrich, MPH, RAC
Lieutenant Commander, US Public Health Service
Senior Regulatory Review Officer
Biological Drug and Device Compliance Branch
DHHS, FDA, CBER, Office of Compliance and Biologics Quality
Tel: 240-402-8876

From: Jones, Cecily
Sent: Wednesday, September 27, 2017 11:53 AM
To: CBER Complicheck <complcheck@fda.hhs.gov>
Subject: RE: Compliance Check for Original BLA STN 125653/0

FEI: 3004141078

Pleasanton, CA

From: CBER Complicheck
Sent: Wednesday, September 27, 2017 11:36 AM
To: Jones, Cecily <Cecily.Jones@fda.hhs.gov>
Subject: RE: Compliance Check for Original BLA STN 125653/0

Hi there,

Do you have an FEI for the CA location as well?

From: Jones, Cecily
Sent: Tuesday, September 12, 2017 4:07 PM
To: CBER Complicheck <complcheck@fda.hhs.gov>
Subject: Compliance Check for Original BLA STN 125653/0

Please execute a compliance check.

Applicant Name: Roche Molecular Systems, Inc.
License Number: 1636
Application Number: **125653/0**
Applicant Address: Roche Molecular Systems, Inc.
4300 Hacienda Drive
P.O. Box 9002
Pleasanton, CA 94588-0900

Product: cobas[®] Zika
Action Due Date: **October 6, 2017**
Short Summary: cobas[®] Zika is a qualitative test that is run on the cobas[®] 6800 System and cobas[®] 8800 System. cobas[®] Zika enables the simultaneous detection of Zika RNA and the internal control in a single test of an infected, individual donation.

Firm: [Roche Molecular Systems, Inc.](#)

(b) (4)



Thank you,

Cecily

CDR Cecily Jones, USPHS
Director, Regulatory Review Officer
Division of Manufacturing and Product Quality
OCBQ, CBER, Food and Drug Administration
10903 New Hampshire Ave., Bldg. 71, Rm. 6023
Silver Spring, MD 20993-0002
Main: (240) 402-9168 Ofc: (240) 402-9613 Fax: (301) 595-1306
Cecily.Jones@fda.hhs.gov