

From: Beshir, Leyla
Sent: Thursday, September 28, 2017 3:44 PM
To: Kumar, Vasantha
Cc: Quander III, Joseph
Subject: RE: Lot Release clearance requested: STN 125653/0. ACTION DUE DATE: 6 October 2017

Follow Up Flag: Follow up
Flag Status: Flagged

Please Note,

A review of PRB records indicate that there are no pending lots or issues that would affect approval of the stated STN.

125653/0

Leyla Beshir

Biologist, Product Release Branch
CBER/OCBQ/DMPQ
WO, Building 75, Room G708
240-402-9165 (main)/ 240-402-5839 (office)/301-595-1253 (fax)
[Lot Release Information](#)

From: Kumar, Vasantha
Sent: Thursday, September 28, 2017 3:06 PM
To: CBER Lot Clearance <cberlotclearance@fda.gov>
Subject: Lot Release clearance requested: STN 125653/0. ACTION DUE DATE: 6 October 2017
Importance: High

Please confirm there are no lots associated with this BLA

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)

A large rectangular area of the document is redacted with a solid grey fill, obscuring several lines of text.

Vasantha

Vasantha Kumar, Ph.D.

Regulatory Project Manager

Center for Biologics Evaluation and Research
Office of Blood Research and Review
U.S. Food and Drug Administration
WO 71/Room 4206
Tel: 240-402-8413

Vasantha.Kumar@fda.hhs.gov

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