Australian Government

Department of Health
Therapeutic Goods Administration

Jason Maness
ViroMed Laboratories Inc
1447 York Court
Burlington NC 27215
United States Of America

Our Reference: 2014/044406

Dear Mr Maness,

Subject: Issue of GMP certificate MI-2014-CE-07367-1

Please find enclosed the GMP certificate for your manufacturing premises.

You may note its changed layout with new security provisions: blue and grey curved dotted lines at the bottom half of each page. These provisions are intended to prevent unauthorised copying as part of a process to introduce issuing certificates electronically in the near future. This will also include using electronic signatures only.

The certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration. The inspection frequency is not a reflection of the expiry date shown on the certificate but is consistent with the re-inspection frequency applicable to Australian manufacturers of the same class of products.

The Therapeutic Goods Administration will contact the relevant sponsor/s to arrange the re-inspection of your facility.

Yours sincerely,

Jenny Hantzinikolas
Manufacturing Quality Branch

1 June 2015

Contact: Susanne Douglas, phone +61 3 8687 5004 and fax +61 2 6203 1527

Australian Government

Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2014-CE-07367-1

Issued to:

ViroMed Laboratories Inc

Manufacturing Site Address:

1447 York Court

Burlington North Carolina 27215

UNITED STATES OF AMERICA

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer has been inspected following section 32EA(1) of the *Therapeutic Goods Act 1989* in connection with manufacturers of Biologicals (items made from or containing human cells or human tissues) located outside Australia.

From the knowledge gained during inspection of this manufacturer, the latest of, that was conducted on 05 to 08 January 2015, it is considered that the manufacturer complies with the Good Manufacturing Practice (GMP) requirements of the Australian Code of Good Manufacturing Practice for Human Blood and Tissues (2000).

This certificate reflects the status of the manufacturing site at the time of the inspection noted above. This certificate remains valid until the expiry date provided that re-inspections are conducted as determined by the Therapeutic Goods Administration as the issuing Authority. This certificate should not be relied upon to reflect the compliance status after the expiry date.

EXPIRY DATE: 07 January 2017

ISSUE DATE: 1 June 2015

Name and signature of an authorised person of the Competent Authority of Australia:

Signed: .....

Jenny Hantzinikolas
Manufacturing Quality Branch

This certificate is valid only if the security provisions (blue and grey curved dotted lines on the bottom half of each page) are visible.

This certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration.

The authenticity of this certificate may be verified with the Therapeutic Goods Administration as the issuing authority.

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 02 6232 8444 Fax: 02 6232 8605 Email: info@tga.gov.au www.tga.gov.au

TGA Health Safety Regulation

Australian Government

Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2014-CE-07367-1

MANUFACTURING OPERATIONS

This certificate covers the following steps in the manufacture of therapeutic goods at the manufacturing site address specified above.

Manufacturing Type	Product Category	Manufacturing Step
Testing Laboratory – Blood, Tissue, Cellular	Not Applicable	Virology Screening and Syphilis Testing NAT Testing for HIV, HCV and HBV

Name and signature of an authorised person of the Competent Authority of Australia:

Signed: .....

Jenny Hantzinikolas
Manufacturing Quality Branch

This certificate is valid only if the security provisions (blue and grey curved dotted lines on the bottom half of each page) are visible.
This certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration.
The authenticity of this certificate may be verified with the Therapeutic Goods Administration as the issuing authority.

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