Austrian
Federal Office for
Safety in Health Care
BASG

BASG / AGES MEA
Institute Surveillance
Traiseng. 5, 1200 Vienna, Austria

Octapharma Pharmazeutika Produktionsges.m.b.H
Michaela Ryba
Oberlaaerstraße 235
1100 Wien
Österreich

Date: 21.12.2020
Contact: Dr. Michael Zwitkovits
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Our reference: INS-482518-13518398-16506783

INSPECTION OF THIRD COUNTRY SOURCE PLASMA / RECOVERED PLASMA SITES FOR Octapharma Pharmazeutika Produktions GmbH

Dear Michaela Ryba,

We refer to the inspection performed for your company at National Genetics Institute (NGI), 2440 S. Sepulveda Boulevard Suite 235 and 2311 Pontius Avenue, 90064 CA Los Angeles premises on 26 - 27 October 2017 by the Federal Office for Safety in Healthcare (BASG).

On the basis of the inspection performed on 26 – 27 October 2017, and subsequent correspondence, we can confirm that operations relating to the safety and quality of plasma are in general compliance with the requirements of Commission Directives 2004/33/EC and 2005/62/EC implementing Directive 2002/98/EC of the European Parliament and of the Council, the relevant European Pharmacopoeia Monograph(s) and Directive 2003/94/EC.

This letter reflects the status of the plasma collection site at the time of the inspection noted above. The Issuing Authority has established appropriate inspection and control measures for the above named site(s) to deem it compliant until **December 2022**. This letter should not be relied upon to reflect the compliance status if the above mentioned date has been exceeded, after which the issuing authority should be consulted.

The listing of this site in **EMEA/H/PMF/000008/05** is recommended.

Any matters arising from this inspection will be reviewed at the next inspection.

Due to the restrictions caused by COVID-19, the period of validity of the statement of next inspection in effect at the time of declaration of the pandemic by WHO is extended applying inspection and control measures in line with EMA recommendation EMA/INS/GMP/534269/2018 " Application of inspection and control measures to facilitate risk-based inspection planning of sites within the Plasma Master File (PMF) certification system". On-site inspections will resume as soon as there is a consensus that the period of the public health crisis has passed. The clarifying remark section of individual SONIs will indicate any exceptions. Competent authorities reserve the right to inspect a blood establishment should the need arise.

On behalf of the Austrian Federal Office for Safety in Health Care

see official signature right at the end of this document

BASG / AGES MEA
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Traiseng. 5, 1200 Vienna, Austria

Kraßnigg Andreas
am 23.12.2020

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