

U.S. Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Avenue
W071, G112
Silver Spring, MD 20993-0002

October 22, 2021

WILATE (von Willebrand Factor / Coagulation Factor VIII Complex [Human])**STN: 125251****RESPONSE TO PREA NON-COMPLIANCE LETTER****dated September 8, 2021****(STN 125251/272)**

Required Pediatric Assessment(s)

Prior Approval Supplement - Efficacy Supplement

- Hemophilia A indication in children (clinical study WIL-30)
- Extension of shelf-life after reconstitution of the Wilate powder in diluent from immediately to **(b) (4)**

eCTD sequence 0210

Dear Ms. Tran,

We refer to the notification of non-compliance with PREA dated September 8, 2021 for STN 125251/272.

Please find enclosed our **RESPONSE TO PREA NON-COMPLIANCE LETTER**.

Please contact Dr. Barbara Rangetiner, Management International Drug Regulatory Affairs, email: barbara.rangetiner@octapharma.com, tel: 011 431 61032 1266 for any questions or requests regarding this submission.

Octapharma agrees to receive information by email from OTAT.

The electronic media were scanned and certified as virus free using Symantec Endpoint Protection Antivirus software, according to the current version. The antivirus library will be updated daily (automated process).

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Rechtsform: Gesellschaft m.b.H.
Sitz des Unternehmens: Wien
UID-Nr.: ATU 14253608
Firmenbuchnummer: FN 63568 h
Firmenbuchgericht: HG Wien
DVR-Nr.: 0599379

Kind regards
OCTAPHARMA Pharmazeutika
Produktionsges.m.b.H

/s/

Dr. Barbara Rangetiner
(Director Int. Drug Regulatory Affairs)

/s/

Nina Prieß
(Int. Drug Regulatory Affairs Manager)

cc: Stanley Ammons, Octapharma USA Inc.

Sent via electronic gateway

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