

From: [Glen, Jacqueline](#)
To: [Qian, Jiahua](#)
Cc: [Quander III, Joseph](#)
Subject: RE: OBRR Lot release / clearance request: STN 125555/0
Date: Monday, August 24, 2015 5:42:34 PM

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

Thank you
Jackie

Jacqueline Glen Consumer
Safety Officer
PRB/OCBQ/CBER/FDA/HHS
WO, Building 71, Room 6052
240-402-9558
240-402-9165 main
301-595-1253 fax
Jacqueline.glen@fda.hhs.gov

From: Qian, Jiahua
Sent: Monday, August 24, 2015 10:32 AM
To: CBER Lot Clearance
Cc: CBER Lot Release
Subject: OBRR Lot release / clearance request: STN 125555/0

Please confirm that there are no issues associated with this original submission

1. The requestor's office: **OBRR**
2. STN: **125555/0**
3. The manufacturer's license number **1646**
Manufacturer's name: **Octapharma**
4. The Licensed name of the product and not the trade name: **Antihemophilic Factor (Recombinant)**
5. The Submission Type and Subtype. **Original BLA**
6. The Action Due Date; **4-September-15**

A Short Summary of the licensing action: Indicated in adults and children with Hemophilia A for:

- On-demand treatment and control of bleeding episodes
- Perioperative management of bleeding
- Routine prophylaxis to prevent or reduce the frequency of bleeding episodes

Thank you

Jiahua Qian, Ph.D.
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