

**From:** [Six, Melanie](#)  
**To:** [Qian, Jiahua](#)  
**Cc:** [Rangetiner, Barbara](#); [Hollaus, Marianne](#); [Ammons, Stanley](#)  
**Subject:** Re: FDA advice: OCTAPHARMA , STN BLA 125555/0  
**Date:** Friday, July 25, 2014 3:04:14 AM  
**Attachments:** [image001.png](#)

---

Dear Jiahua,

We take note of your advice and will use the terms “Antihemophilic Factor (Recombinant) - rAHF” and “B-domain deleted recombinant Factor VIII - BDD-rVIII” in future discussions of information and data.

Kind regards,

Melanie

Melanie Six  
Int. Drug Regulatory Affairs Manager

---

**octapharma®**

For the safe and optimal use of human proteins

Octapharma Pharmazeutika Produktionsges.m.b.H | Oberlaaer Strasse 235 | A-1100 Vienna Austria |  
Office: +43 1 61032 1267 | Fax: +43 1 61032 9122 | [melanie.six@octapharma.com](mailto:melanie.six@octapharma.com) | [www.octapharma.com](http://www.octapharma.com) |  
FN 63568 h | HG Wien | UID ATU 14253608

Please consider the environment before printing this e-mail.

CONFIDENTIALITY NOTICE: This communication is intended to be confidential to the person(s) to whom it is. If you have received this communication in error, please advise the sender immediately by telephone and delete this message and any attachments without retaining a copy.

---

**From:** Qian, Jiahua [mailto:[Jiahua.Qian@fda.hhs.gov](mailto:Jiahua.Qian@fda.hhs.gov)]  
**Sent:** Thursday, July 24, 2014 4:36 PM  
**To:** Knaub, Sigurd  
**Cc:** Rangetiner, Barbara; Hollaus, Marianne; Ammons, Stanley; Walter, Olaf; Thibaut, Ulrich  
**Subject:** FDA advice: OCTAPHARMA , STN BLA 125555/0

Dear Barbara and Sigurd

We are reviewing your original BLA STN 125555/0 and have the following advice regarding the assigned proper name for their product and the standard abbreviation for references to the active ingredient.

Please be advised that the proper name assigned to your product is, “Antihemophilic Factor (Recombinant),” which may be abbreviated rAHF. The active ingredient in your product is a B-domain deleted recombinant Factor VIII; therefore, discussions of information and data pertaining to the drug substance may use the abbreviation, BDD-rFVIII. Please discontinue using the reference, “recombinant human Factor VIII.”

Thank you  
Jiahua Qian Ph.D.

CBER/OBRR  
240 402 8432

---

This email has been scanned by the (b) (4) .  
For more information please visit (b) (4)

---

---

This email has been scanned by the (b) (4)  
For more information please visit (b) (4)

---