

From: Krammer, Marlene <marlene.krammer@octapharma.com>
Sent: Friday, April 17, 2015 8:33 AM
To: Hooban, Christopher
Cc: Ammons, Stanley; Rangetiner, Barbara
Subject: RE: Facility Information: FEI Numbers - STN 125587/0; Original BLA Application

Dear Mr. Hooban,

I refer to your Email to Mr. Ammons of today. Please find enclosed the FEI numbers for all facilities associated with our original BLA Application (FDA STN: 125587/0) submitted on 15 April 2015.

Octapharma, 72 rue du Maréchal Foch, 67380 Lingolsheim, France: not FDA licensed yet
Operations performed: plasma to final container

Octapharma Pharmazeutika Produktionsges.m.b.H., Oberlaaer Strasse 235, 1100 Vienna, Austria: FEI: 3002809097
Operations performed: filling, visual inspection, labelling, packaging

Octapharma GmbH Dessau, Otto-Reuter-Str. 3, 06847 Dessau, Germany: FEI: 3008923644
Operations performed: visual inspection, labelling, packaging

Kind regards,

Marlene Krammer
Manager
International Regulatory Affairs Department

Octapharma Pharmazeutika Prod.ges.m.b.H. | Oberlaaer Strasse 235 | A-1100 Vienna Austria |
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From: Hooban, Christopher [mailto:Christopher.Hooban@fda.hhs.gov]
Sent: Friday, April 17, 2015 8:19 AM
To: Ammons, Stanley
Cc: Cagungun, Nannette
Subject: Facility Information: FEI Numbers - STN 125587/0; Original BLA Application

Mr. Ammons,

Good morning. Please provide FEI numbers for all facilities associated with your Original BLA Application (FDA STN: 125587/0) submitted 15 April 2015. Thank you for your time.

Chris Hooban
Regulatory Project Manager

U.S. Food & Drug Administration
White Oak Building 71, Room 4257
Office: (240)402-8376
Mobile: (240)762-2266
Email: christopher.hooban@fda.hhs.gov

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