

# RECORD OF TELEPHONE CONVERSATION

## Submission Information

<b>Application Type</b>	BLA
<b>STN</b>	125587/0.0
<b>Review Office</b>	OBRR
<b>Applicant</b>	Octapharma Pharmazeutika Produktionsges.m.b.H. / Lic. # 1646
<b>Product</b>	Immune Globulin Intravenous (Human)
<b>Trans-BLA Group:</b>	No

## Telecon Details

<b>Telecon Date/Time</b>	29-OCT-2015 9:00 AM
<b>Author</b>	HOOBAN, CHRISTOPHER
<b>EDR</b>	Yes
<b>Post to Web</b>	No
<b>Outside Phone Number</b>	1-866-380-4181
<b>FDA Originated?</b>	Yes
<b>Communication Categories</b>	OT -
<b>Related STNs</b>	None
<b>Related PMCs</b>	None
<b>Telecon Summary</b>	Discussion of responses provided by applicant in amendment 8 and 17. Applicant agreed to respond to any unanswered questions via written communication.
<b>FDA Participants</b>	Christopher Hooban Michael Kennedy Christian Lynch Randa Melhem

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<b>Applicant Participants</b>	<p>Octapharma, Austria</p> <ul style="list-style-type: none"> <li>• Karl Leitner – Plant Manager</li> <li>• Günter Iberer – Head of Production</li> <li>• Werner Giefing – Head of Quality Assurance</li> <li>• Harald Mayer – Head of Operation Support</li> <li>• Andreas Summerer – Head of Pharmaceutical Production</li> <li>• Friedrich Kienesberger – Head of Aseptic Production</li> <li>• Barbara Rangetiner – Head of Regulatory Affairs</li> <li>• Rita Gorsche – Regulatory Affairs Manager</li> <li>• Marlene Krammer – Regulatory Affairs Manager</li> </ul> <p>Octapharma, USA</p> <ul style="list-style-type: none"> <li>• Stanley Ammons – Senior Director, Compliance &amp; Government Policy</li> </ul>
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### Telecon Body:

Christian Lynch asked the firm to correct the FEI number for the Lingolsheim OSA facility to the parent FEI# 3010600159.

Randa Melhem requested further clarification to responses provided to information requests sent on June 23 (response provided as amendment 8) and September 23 (response provided as amendment 17). The applicant was able to provide acceptable clarification to some of the questions (itemized below). Those questions that were not answered will be sent to the applicant as an information request. Randa requested that the applicant provide adequate information and clarification to each question of the information request to prevent the need for more teleconferences and additional information requests.

CBER questions are in *italics* followed by the responses in plain lettering.

1. *You reported that some of the stoppers used on filling line-(b) (4) are washed and sterilized in (b) (4). Has this information been submitted previously in association with other licensed products?*

Octapharma responded that the information was submitted and reviewed by FDA for the licensed Albumin and Octagam products.

2. *You reported for the sterilization of stoppers that “program (b) (4) is used to sterilize stoppers and equipment used at filling line-(b) (4) and filling line-(b) (4)”. Is there a filling line-(b) (4) ?*

Octapharma clarified that there is filling line-(b) (4) used for small volume parenterals but it is not used for filling NewGam.

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3. *For the validation of the vial washer you reported that (b) (4) vials are sampled – (b) (4) from the (b) (4). Do you mean vials held at (b) (4) position as shown in Fig 2 (amendment 17): the vial gripper of washing machine (b) (4) showing (b) (4) position allowing for (b) (4) vials to be washed in (b) (4)?*

Octapharma stated that they meant the (b) (4) positions.

4. *You reported that acceptance criterion for the (b) (4) for the (b) (4), and you explained in amendment 17 that “(b) (4)” is collected (b) (4) glass vial surface, and thus the tighter limit ((b) (4)) is not justified considering that the manufacture of the vials does not take “place in a microbiological/physical controlled area and vials might furthermore be subjected to manual visual inspection”. Review of the data shows no microorganisms ((b) (4)) were detected during sampling. The acceptance criteria should reflect process capabilities.*

Octapharma explained that the limits were set prior to the validation studies and that they will take a second look and re-evaluate the acceptance criteria for (b) (4).

5. *You provided (in amendment 8) the (b) (4) validation reports for (b) (4) vessels (b) (4). Please clarify if the vessels are only cleaned by (b) (4).*

Octapharma confirmed that **only** (b) (4) is used for (b) (4) of (b) (4) vessels (b) (4).

6. *For Filling Line (b) (4) – how many vials are filled at a time?*

Octapharma stated that the filling line has (b) (4) needles, and thus (b) (4) vials are filled at a time.

7. *In response to Q6a (amendment 17), you reported that “lying vials” are rejected; is this automatic or performed manually by an operator?*

Octapharma explained that this is an automatic step.

8. *Please specify the color of the NewGam flip caps.*

Octapharma stated that the caps of the small vials are blue, and the caps of the large bottles are white.