RECORD OF TELEPHONE CONVERSATION

Submission ID: *125612/0*
Office: *OBRR*

Title: *FIBRYNA Human Fibrinogen*
Sponsor: *Octapharma Pharmazutika*

Telecon Date/Time: *10-NOV-2016 8:45 AM*
Initiated by FDA?: *Yes*
Telephone Number: *(201) 604-1123*
Email?: *No*

Author: *LORRAINE WOOD*

Purpose: *Discussion of iPSP*

FDA Participants:
LORRAINE D WOOD
VICTOR BAUM

Sponsor Participants:
STANLEY AMMONS
JULIANE MAYERHOFER
BARBARA RAGETINER

Amendments: *0 - ORIGINAL SUBMISSION*

Summary of Discussion:

FDA indicated without exception that an iPSP will be required and should have been submitted prior to the submission of the BLA.

Several major points were discussed:

1. *Octapharma felt that this was not a new active ingredient and therefore should not have triggered PREA.*

FDA responded that as a biologic, due to potential manufacturing differences, it would be considered a new active ingredient and would trigger PREA.

2. *Octapharma indicated that as a rare (orphan) disease, this should have excluded consideration by PeRC.*

FDA indicated that while afibrinogenemia is a rare disease, this product is not orphan designated, and official orphan designation by FDA would have been required

3. *Octapharma indicated that the pediatric "assessment" information is present in the BLA.*

FDA indicated that while much of the required information is within the submitted BLA materials it is both in an inadequate format and lacks required information. Examples offered were a missing timeline and the absence of information about the ongoing pediatric trial (FORMA-04).

4. *Octapharma indicated that in July they had received comments about the pediatric protocol. When discussing submission of the iPSP they said that they could respond in a short timeframe with the original protocol, with changes to the protocol to follow. They indicated they could submit an iPSP in three weeks using the original protocol. It is possible to modify that iPSP using the FDA input from July and have it submitted as the Agreed iPSP.*