DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
CBER/OCBQ/DBSQC

From: Alfred Del Grosso, Ph.D. Team Leader Chemistry, LACBRP, DBSQC

Tao Pan, Ph.D. LACBRP, DBSQC

Subject: Test Results for Residual Moisture for Octapharma Fibrinogen (Human) Drug Product Samples **STN: 125612/0**

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To: File STN 125612/0

Through: James Kenney, D.Sc. Acting Director DBSQC

William McCormick, Ph.D. Director DBSQC

Summary of Testing:

Test results for residual moisture by DBSQC and Octapharma comply with the proposed drug product specification.

1) Residual Moisture (CBER TMID 000476)

Determination of residual moisture content was performed by CBER using Karl Fischer coulometric titration with methanol extraction of the lyophilized sample (DBSQC Test Method Doc. ID 000476). Each lot result represents the average of three titrations, each from the extracted contents of two vials that were assayed individually. As described in the BLA, the sponsor determines moisture using a method similar to CBER's that is consistent with (b) (4) .

CBER Analyst was Tao Pan.

Table 1 – Residual Moisture

	CBER		Octapharma
Lot#	% w/w Moisture	Test Date	(b) (4) Moisture
A425A3471	0.6	01/12/17	1
A423A3472	0.3	01/12/17	1
A433A3423	0.5	01/12/17	1
A441A3474	0.5	01/12/17	1
A440A3472	0.5	01/12/17	1

Octapharma has specified a release limit for residual moisture of (b) (4) for this product. CBER test results for these lots meet this criterion along with test

results submitted by the sponsor.