Ali Hamidi

From: Libeg, Meredith <[redacted]>
Sent: Wednesday, April 29, 2015 3:13 PM
To: Ebrahim S. Delpassand
Cc: Keegan, Patricia; Ali Hamidi
Subject: RE: 78,256

Sensitivity: Confidential

Hi Dr. Delpassand,
As discussed at the teleconference yesterday, in order to not penalize the patients who signed consent, you may continue the planned treatment course for the 6 patients that Ms. White identified as having signed the informed consent document on the following days:

2 patients on March 18, 2015
1 patient on March 24, 2015
1 patient on April 1, 2015
2 patients on April 7, 2015

Should you have any questions, please don't hesitate to contact me; and kindly confirm receipt of this email.

Best regards,
Meredith

Meredith Libeg, P.M.P, R.A.C. (US), C.C.R.P.
Regulatory Project Manager
Division of Oncology Products 2
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research
[redacted]

From: Ebrahim S. Delpassand [[redacted]]
Sent: Tuesday, April 28, 2015 8:23 PM
To: Libeg, Meredith
Cc: Keegan, Patricia; Ali Hamidi
Subject: IND: 78,256
Importance: High
Sensitivity: Confidential

Hi Meredith:

Thank you again for organizing the phone call today. As discussed, please confirm that Dr. Patricia Keegan, Director Division of Oncology Products 2 Office of Hematology and Oncology Products, Center for Drug Evaluation and Research at FDA authorized completion of the full course of treatments on patients enrolled between March 17th 2015 to April 14th, 2015 to the above IND.

Thank you for your assistance;