octaplas Trial file

OCTAPHARMA

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TELEFAX

To : Dr. A Robinson

From : Keith Lawson

Subject : Octaplas Study Suspension

Fax Number : + 44 GRO-C

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Dear Dr Robinson

Octaplas (SD FFP) v Standard FFP Study Suspension

As you are aware the MCA have suspended the above study.

Although I have had no official communication from the MCA, I have obtained some information from a telephone call I made to their clinical trials department.

Firstly *NO* adverse events have taken place in the UK study or within Europe, where this product is extensively used (approximately 1,500,000 bags of SD FFP), which has necessitated the suspension of the study.

The problem appears to be centred around a product licence application made by Octapharma for a UK Octaplas registration, submitted in November 94. The virus inactivation studies were originally carried out by the New York Blood Centre, as this product was developed by the New York Blood Centre with collaboration from Octapharma. These studies are no longer state of the art as they were carried out over 4 years ago. The bulk of virus inactivation information supplied to the MCA, last November, was based on these studies. A whole raft of new studies performed by Octapharma now exists, although these studies are not in the possession of the MCA. We had intended submitting these studies in answer to questions raised related to the application.

It appears the MCA concerns lie with some of the viral inactivation studies submitted. I have arranged a meeting with the relevant people at the MCA for October 24 th. At this meeting we expect to be able to answer the majority of the questions raised and establish first hand if there are any underlying issues.

I apologise for the significant inconvenience caused but I shall be able to tell you more on October 25th.

I enclose for your interest an updated European FFP Usage table.

Yours sincerely,

GRO-C

Keith Lawson
U.K. Country Manager