PPTA
Plasma Protein Therapeutics Association

28 September 2006
Reference: DGENT06010

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Ms. Georgette Lalis
Director European Commission
Mr. Nicolas Rossignol
DG Enterprise and Industry
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Subject: Revision of "Commission Regulations (EC) No 1084/2003 and (EC) No 1085/2003" and the related "Guideline on dossier requirements for Type IA and Type IB notification (July 2003)".

Dear Ms. Lalis, dear Mr. Rossignol,

PPTA welcomes the Commission's initiative to revise the "Commission Regulations (EC) No 1084/2003 and (EC) No 1085/2003" and the related "Guideline on dossier requirements for Type IA and Type IB notification (July 2003)", because of the serious negative impact on biological products.

We appreciate the opportunity to be part of this important revision process. Our regulatory experts have shared their practical experience on the basis of which we developed the attached "PPTA Concept Paper on the Revision of the Current European Union Variation System" (DGENT06011).

We believe that the early involvement of interested parties, such as patients, physicians and industry, in the decision making processes to develop Commission regulations is important. The European Commission Pharmacovigilance Workshop with Industry on 21 April 2006 was an excellent example for a constructive dialogue between industry and the Commission at an early phase of the decision making process. We believe that sharing our experience with the current variation system with you and your colleagues at an early stage will be helpful for your internal discussion and accelerate the urgently needed revision process of these regulations.

We hope that our proposal outlined in our concept paper will find your consideration and we remain at your disposal for further discussions.

Yours sincerely,

Dr. Ilka von Hoegen
Director, Regulatory Affairs

Enclosure: DGENT06011

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