



European Medicines Agency
Evaluation of Medicines for Human Use

London, 18 November 2005
EMEA/CHMP/GTWP/386718/2005

Dr. Raj Puri
FDA - Center for Biologics Evaluation

Dear Dr Puri,

Subject: FDA draft guidance on Gene Therapy Clinical Trials - Observing Participants for Delayed Adverse Events

The FDA has posted draft guidance on Gene Therapy Clinical Trials - Observing Participants for Delayed Adverse Events for comments by 21st November 2005.

We would like to thank FDA for inviting comments on this very good draft guidance.

Please note our attached comments focussing on scientific aspects. We did not address possible issues related to the different legal frameworks in the EU and US.

We would be pleased to have the opportunity to further discuss with you this draft document at the occasion of the next plenary meeting of the CHMP Gene Therapy Working Party (to be held on 19-20 January 2006), via video/teleconference.

Should you wish any clarifications on the above please do not hesitate to contact Dr Marisa Papaluca-Amati (marisa.papaluca@emea.eu.int) or Dr Laurent Brassart (laurent.brassart@emea.eu.int).

Best regards

A handwritten signature in black ink, appearing to read 'D. Basseur', with a large, sweeping initial 'D'.

Dr Daniel Basseur
CHMP Chairman

Cc: Stephanie L. Simek, M. Limoli, Klaus Cichutek, A. North