


Page 4 – Mr. Paul Weissenberg
Mr. Thomas Lönngren

This arrangement will commence 12 September 2003 for an initial period of two years, and remain in effect until 12 September 2005, during which time we will together assess its effectiveness on at least an annual basis and make any needed revisions.

This letter, together with your letter on behalf of the EMEA and the European Commission, will constitute our mutual commitments to implement these procedures.

We look forward to implementing these procedures that will allow for the sharing of information and to continuing our many cooperative activities to enhance the public health of our regions and to foster further the already beneficial and productive relationship between the EMEA, the European Commission, and the FDA.

Sincerely,

A handwritten signature in black ink, appearing to read 'Mark B. McClellan', with a long horizontal flourish extending to the right.

Mark B. McClellan, M.D., PhD.
Commissioner of Food and Drugs

Enclosure