



04 June 2008

Ms Emer Cooke
Head of Sector, Inspections
European Medicines Agency
7 Westferry Circus
London
E14 4HB
UNITED KINGDOM

Dear Emer:

We thank you for your offer for the US FDA to participate in a draft pilot project with a view towards more coordinated planning of international GMP inspections, with an initial focus on APIs, as outlined in your letter to me of the 7th of April, 2008.

After careful consideration, the US FDA is pleased to accept this invitation and look forward to working on the further refinement and development of this project with you and our other international colleagues who will also be participating.

This kind of purposeful regulatory cooperation and resource leveraging between regulatory agencies similarly dedicated to the mission of the promotion and protection of public health can only benefit the public good internationally.

FDA's points of contact for the pilot project are: Joseph Famulare (technical) joseph.famulare@fda.hhs.gov, Steven Solomon (inspectorate) steven.solomon@fda.hhs.gov, and Michelle Limoli (administrative) michelle.limoli@fda.hhs.gov

Please keep Joe, Steve, and Michelle "in the loop" on all communications about this project, and please feel free to contact me any time if you think my personal engagement would be helpful.

Thank you again for this invitation.

Best personal regards,

A handwritten signature in cursive script that reads "Murray M. Lumpkin".

Murray M. Lumpkin, M.D.
Deputy Commissioner
International and Special Programs