European Medicines Agency
Veterinary Medicines and Inspections

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Mr Murray Lumpkin
Food and Drug Administration
5600 Fishers Lane
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UNITED STATES

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Dear Mr Lumpkin

As you are aware from our discussions during the 2nd Summit of Head of International Regulatory Authorities in Dublin last year, EMEA has recently put together a draft pilot project with a view towards more coordinated planning of international GMP inspections. This was prompted by informal discussions with the European Commission, WHO and some of the Community's MRA partners and the need for this or similar activity has been reinforced in the context of the recent Heparin crisis.

The pilot project is focussed on inspections of active substances (active pharmaceutical ingredients) planned outside the territories concerned but, if successful, could be extended to other types of GXP inspections. The rationale for choosing inspections of active substance was based on the fact that a common GMP standard already exists (ICH Q7A), combined with the fact that there are a large number of suppliers of active substances exporting to EEA, US and MRA partner markets and thus probably a common interest in supervising these suppliers. You may also be aware that a module for inspection planning in non-EEA countries is part of the EudraGMP project currently foreseen for development in 2010.

As one of EMEA's partners most actively performing inspections of active substances we would like to ask whether your authority would also be willing to volunteer to participate in this pilot project. So far we have had a positive response from the French, UK and German authorities as well as EDQM. A response is awaited from Australia. To this end we are enclosing the draft pilot project for your consideration and comments.

Please let me know whether your authority is interested in participating and if possible, provide me with a contact point for further discussion.

Yours sincerely With my best personal regards

Emer Cooke
Head of Sector, Inspections

cc: Dr Michelle C Limoli, Food and Drug Administration, 5600 Fishers Lane, MD 20857 Rockville, USA
Mr Joseph C Famulare, Food and Drug Administration, Montrose Metro #2, 11919 Rockville Pike, MD 20852 Rockville, USA

Attached: pilot project

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