



European Commission

European Agency for the  
Evaluation of Medicinal Products

September 12, 2003

Dear Dr McClellan,

The Food and Drug Administration (FDA) of the United States of America (US) on the one side and European Commission's Directorate General Enterprise and the European Agency for the Evaluation of Medicinal Products (EMA) (collectively "the Participants") on the other side have recognised the need to further improve their relationship and in particular, in the Transatlantic Economic Partnership Action Plan, the need for increased co-operation as a means to address technical barriers to trade in goods. This view was later reflected in the Guidelines on regulatory co-operation and transparency between the US Government and the European Commission. In particular these Guidelines encourage the identification of areas where regulatory co-operation could be established.

One of the specific aims mentioned in the guidelines is to obtain from each other and interested parties the benefit of the expertise, perspectives and ideas for alternative approaches to regulation. In addition the idea of harmonisation of regulatory requirements *ex novo* is specifically highlighted.

There is already considerable experience in the field of regulatory co-operation between the FDA and European Commission administrations responsible for regulation in the pharmaceutical sector. To date, this has been in the context of regular bilateral meetings between representatives of DG Enterprise (since 1989) and representatives of the FDA.

The success of existing regulatory co-operative measures on harmonisation of technical requirements and an agreement on a common format for the submission of certain regulatory information to the respective pharmaceutical regulatory authorities has led to the desire from both sides to increase the range of information that can be shared in the interests of better regulatory co-operation.

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