



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

September 12, 2003

Mr. Paul Weissenberg
Director, Directorate F
European Commission
rue de la Loi
B-1049 Brussels
BELGIUM

Mr. Thomas Lönngren
Executive Director
The European Agency for the
Evaluation of Medicinal Products
7 Westferry Circus
Canary Wharf
London, E14 4HB
UNITED KINGDOM

Dear Mr. Weissenberg and Mr. Lönngren:

The Food and Drug Administration (FDA) is pleased to cooperate with the European Commission (in its pharmaceutical regulation capacity) and The European Agency for the Evaluation of Medicinal Products (EMA) (collectively "the Participants") to facilitate the sharing of documents and/or information related to assuring the safety, quality, and efficacy of pharmaceutical products intended for (a) human use (including biological products and orphan drugs) or (b) animal use. This information-sharing arrangement is intended, among other things, to provide for the exchange of information between our staffs during the review and evaluation of investigational and marketing applications and the post-marketing surveillance of these products. We expect this cooperative activity to further enhance and strengthen communication between our respective organizations and further enhance public health promotion and protection in the European Union (EU) and the United States of America (USA). This arrangement should further the types of public health-related cooperative activities envisioned under the Guidelines on Regulatory Cooperation and Transparency developed by the EU and the USA under the Transatlantic Economic Partnership.

The types of information that may be shared include, but are not limited to, the following:

1. Drafts of pending laws, regulations, guidance documents, procedures and other technical documents available to the individual Participants related to pharmaceutical products (as defined in the previous paragraph).