



U.S. Food and Drug Administration



European Commission



European Agency for the Evaluation of Medicinal Products

**EXTENSION OF CONFIDENTIALITY ARRANGEMENT
BETWEEN THE UNITED STATES FOOD AND DRUG ADMINISTRATION
AND THE EUROPEAN COMMISSION ENTERPRISE AND INDUSTRY
DIRECTORATE-GENERAL AND THE EUROPEAN MEDICINES AGENCY
TO EXCHANGE REGULATORY INFORMATION**

Whereas the United States Food and Drug Administration (USFDA) and the European Commission's Enterprise and Industry Directorate-General (DG Enterprise) and the European Medicines Agency (EMA) (collectively, the Participants) exchanged letters on September 12, 2003 establishing a Confidentiality Arrangement to exchange regulatory information; and

Whereas it was agreed between the participants that the Confidentiality Arrangement was intended to be in effect for a period of two years, at the completion of which the Participants would assess the arrangement's effectiveness; and

Whereas the Participants have assessed the effectiveness of the Confidentiality Arrangement and found that it is a useful tool in transatlantic regulatory cooperation;

The Confidentiality Arrangement, in annex to this extension, is hereby extended for a period of five years from the last date of signature of this document.

Lester M. Crawford, D.V.M., Ph.D.
Commissioner of Food and Drugs
United States Food and Drug Administration

Date: SEP - 7 2005

Georgette Lalis
Director, Directorate F
Enterprise and Industry Directorate-General
European Commission

Date: Sept 12 2005

Thomas Lönngren
Executive Director
European Medicines Agency

Date: Sept 15 2005