

Page 2 – Mr. Paul Weissenberg  
Mr. Thomas Lönngren

2. Post-marketing data and information that could have an impact on the public health, such as pharmacovigilance data or information about impending regulatory actions.
3. Information on quality defect or product recalls of pharmaceutical products, known by the FDA to have been manufactured or distributed in the EU, and vice versa.
4. Information contained in or related to marketing or investigational applications for human or animal pharmaceutical products, as well as information related to orphan drug designations. This also includes information on maximum residue levels in these applications.
5. Without prejudice to arrangements set out in the framework of the Pharmaceutical Good Manufacturing Practices Annex to the Agreement on Mutual Recognition between the USA and the European Community, inspection reports and product sample test results describing the compliance of a pharmaceutical product or manufacturing facility with regulatory requirements.
6. Good Clinical Practices (GCP) inspection reports of clinical trial sites.
7. Information technology information supporting the regulatory process.

There also may be occasions when scientific experts from the Participants will visit each other's agencies and will have access to non-public information. We have, therefore, enclosed an example of the Visitor Commitment Statement that visitors from the EMEA or the European Commission would be required to sign while visiting FDA if they are to have access to non-public information during the visit. We understand that FDA visitors to the EMEA or the European Commission would sign a similar commitment if, during their visit to the EMEA or the European Commission, they are to have access to non-public information.

Both Participants note that it is an essential element of this international arrangement on regulatory cooperation that confidential information emanating from the other Participant will be treated as such.

On each occasion where there is a request for disclosure to third parties of non-public information received from EMEA or the European Commission, FDA shall consult with the EMEA or the European Commission. Likewise, on each occasion where there is a request for disclosure of non-public information received from FDA, the EMEA or the European Commission shall consult with the FDA.