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 (EMEA) (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).

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.

Some of the information identified above may contain non-public information, such as confidential commercial information; trade secret information; personal privacy information; law enforcement information; or internal, pre-decisional information. FDA may only share these types of information as permitted by USA laws and FDA regulations. Among other things, FDA regulations require that a foreign government agency provide written assurance to FDA that it has the authority to protect non-public information from public disclosure and that it will not disclose such information. The EMEA and the European Commission have provided a statement to FDA affirming their authority to maintain the confidentiality of non-public information provided by FDA to their officials or representatives under Article 4.1(a) of Regulation (EC) 1049/2001, which protects non-public information from further disclosure. The EMEA and the European Commission agree that "confidential commercial information" includes information referred to in the US Freedom of Information Act, 5 U.S.C. § 552(b)(4), and in Regulation (EC) No. 1049/2001.

Similarly, FDA affirms that it has the authority to protect the confidentiality of the non-public information identified above under the Freedom of Information Act (FOIA) (5 U.S.C. § 552); the Trade Secrets Act (18 U.S.C. § 1905); section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.§ 331(j)); and other applicable laws. Under the FOIA, the above non-public information shared by the EMEA or the European Commission with FDA is the type of information that can be withheld from public disclosure. FDA, therefore, in accordance with these statutes, consents not to disclose such non-public information provided to FDA by the EMEA or the European Commission absent the written permission of the sponsor/owner of the non-public information or written confirmation by the EMEA or the European Commission that the non-public information no longer has confidential status. The FDA agrees that "confidential commercial information" includes information referred to in the US Freedom of Information Act, 5 U.S.C. § 552(b)(4), and in Regulation (EC) No. 1049/2001.

Sharing of non-public information under this arrangement is in the interest of the public health by reason of the EMEA's or the European Commission's possessing information concerning the safety, efficacy, or quality of a product or information concerning an investigation. Further, the exchange of non-public information under this arrangement is reasonably necessary to facilitate cooperative regulatory activities between FDA, on the one hand, and the EMEA and the European Commission, on the other hand. All non-public information will be shared with the EMEA and the European Commission under this agreement in accordance with Title 21 of the Code of Federal regulations § 20.89.

This cooperative arrangement is not intended to compromise any of the Participants' abilities to carry out their responsibilities and is not intended to create any kind of legal obligation under international or other law on the part of the USA, the FDA, the European Commission, the EMEA, or the European Union.

This arrangement will commence 12 September 2003 for an initial period of two years, and remain in effect until 12 September 2005, during which time we will together assess its effectiveness on at least an annual basis and make any needed revisions.

This letter, together with your letter on behalf of the EMEA and the European Commission, will constitute our mutual commitments to implement these procedures.

We look forward to implementing these procedures that will allow for the sharing of information and to continuing our many cooperative activities to enhance the public health of our regions and to foster further the already beneficial and productive relationship between the EMEA, the European Commission, and the FDA.

Sincerely,

Mark B. McClellan, M.D., PhD.
Commissioner of Food and Drugs

Enclosure

# VISITOR COMMITMENT TO PROTECT NON-PUBLIC INFORMATION[1]

I, _____, a representative of _____
_____, am on an official visit at the United States Food and Drug Administration (FDA). During the course of my visit, I understand that I may have access to non-public information, including confidential commercial information, trade secret information, and internal non-public FDA information. I agree to protect all non-public information to which I have access in the following manner:

1. Store the non-public information in the secured offices of FDA, unless released to me by appropriate FDA officials; and

2. Grant access to this information only to known employees of FDA or to such other persons as may be designated in writing by FDA.

Further, I agree to:

1. Assist in reviewing the security measures I will employ in protecting non-public information;

2. Return all non-public information and any notes related to this information to FDA either upon request by FDA or, at the latest, upon completion of my visit;

3. Report to an FDA official all incidents in which unauthorized persons might have gained access to non-public information made available to me; and

4. Not disclose, publish, or share such non-public information without the express permission of FDA.

Furthermore, I have no financial interest in any manufacturer of a human or animal drug product.

I understand that I may be subject to criminal penalties if I disclose non-public information without auathorization.

_____

SIGNATURE DATE

TYPED OR PRINTED NAME OF
VISITOR:_____

_____

WITNESSED (SIGNATURE) DATE

[1] This document satisfies the requirements of Title 21 of the Code of Federal Regulations § 20.89 (c)(1)(ii)(C) relating to a foreign scientist visiting the Food and Drug Administration on the agency's premises as part of a joint review or long-term cooperative training effort authorized under section 708 of the Federal Food, Drug, and Cosmetic Act.