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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–04–8002]

Exchange of Letters Between the Food and Drug Administration and the European Commission and the European Agency for the Evaluation of Medicinal Products Concerning the Sharing of Documents and/or Information Related to Assuring the Safety, Quality, and Efficacy of Pharmaceutical Products Intended for Human or Animal Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of an exchange of letters between FDA and the European Commission and the European Agency for the Evaluation of Medicinal Products (EMEA). The participants concluded this exchange of letters on September 12, 2003. These letters express the intentions of FDA, the European Commission, and EMEA to continue cooperative activities to further enhance and strengthen communication between the respective organizations and further enhance public health promotion and protection in the European Union and the United States of America.

DATES: The agreement became effective September 12, 2003.

FOR FURTHER INFORMATION CONTACT: Michelle Limoli, European Commission Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0908.

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SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and memoranda of understanding between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this exchange of letters.

Dated: 12/18/03

December 18, 2003.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[INSERT AGREEMENT]

[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

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CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

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.

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 (EMEA) (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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In this context, and within the scope of the guidelines on regulatory co-operation, the European Commission together with the EMEA and the FDA see value in establishing an arrangement to exchange more regulatory information including advance drafts of legislation and/or regulatory guidance documents as well as information related to the authorisation and supervision of medicinal products. Because this type of information may include information of a non-public nature, both sides agree, to the extent permitted by their respective laws, to keep the information exchanged confidential.

The potential benefits of this exercise are expected to include accelerated access of patients to new and innovative medicines; resource savings due to reduced duplication of assessment and improved performance and safety as a result of the involvement of the best regulatory expertise from both sides. This co-operation shall not compromise each Participant's ability to carry out its responsibilities and shall not create any kind of legal obligation on the part of the FDA, the European Commission, or the EMEA.

Therefore the European Commission and the EMEA are pleased to cooperate with the FDA to facilitate the sharing of documents and/or information related to ensuring the safety, quality, and efficacy of medicinal products for human and veterinary use, including orphan medicinal products, authorised or under review both in the US and in the European Union (EU). This is also intended to include information on maximum residue limits.

In this context, the term 'medicinal products authorised in the European Union' refers to products subject to evaluation or authorised under the centralised procedure as well as medicinal products authorised at national level by the EU Member States that are subject to official European Community arbitration and referrals.

This cooperation activity will strengthen communication between public authorities involved in these activities and reinforce public health protection.

The type of information that may be shared includes, but is not limited to:

1. All legislation and guidance documents available under the rules and regulations governing medicinal products in the EU (http://dg3.eudra.org/F2/eudralex/index.htm). This also includes all position papers, notes for guidance and any other guidance documents either in draft, finalised or released for consultation.

2. Post-authorisation pharmacovigilance data, particularly those of urgent nature related to EU or non-EU originating adverse drug reactions as well as safety concerns arising from periodic safety update reports and post-authorisation obligations and commitments.

3. Information on quality defect or product recalls for medicinal products known to the EMEA or to the European Commission to have been manufactured or distributed in the US.

4. Information contained in applications for scientific advice, orphan medicine designation, marketing authorisation or post-authorisation activities of significant public health interest, and maximum residue limits.

5. Without prejudice to arrangements set out in the framework of the US-EC Mutual Recognition Agreement in particular its Sectorial Annex on Pharmaceutical

Good Manufacturing Practices (GMP), GMP Inspection reports and product sample results available to the EMEA or the European Commission.

6. Good Clinical Practices (GCP) inspections for specific products and GCP Inspection reports available to the EMEA or the European Commission.

7. Information Technology systems supporting regulatory processes.

At the EMEA, the information may be shared with national experts on secondment from the EU Member States, EEA countries, or EU candidate countries. These individuals will be required to sign a confidentiality undertaking with the EMEA (form to be annexed). This form will also be completed by each FDA staff member visiting the EMEA.

The Participants reserve the right to limit the scope of the above information should its dissemination or exchange undermine specific interests, including commercial, industrial or professional secrecy, the protection of the individual and of privacy, the public interests of the EU or the protection of the EMEA or the European Commission's interests in the confidentiality of its proceedings. In some cases, exchange of information under this arrangement may be subject to prior authorisation from the companies concerned.

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.

The EMEA and the European Commission affirm that they have the authority to protect non-public information, including confidential commercial information, provided to their officials or representatives by the FDA, and will protect such information as information not to be disclosed under Article 4.1(a) of Regulation (EC) No 1049/2001. The EMEA and the European Commission understand that the FDA considers it crucial that this non-public information be protected from disclosure; otherwise, it could endanger the international relations between the Participants. 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, the FDA affirms that it has the authority to protect non-public information, including confidential commercial information, provided to its officials or representatives by the EMEA or the European Commission, and will protect such information as information not to be disclosed under the US Freedom of Information Act. The FDA understands that the EMEA and the European Commission consider it crucial that this non-public information be protected from disclosure; otherwise, it could endanger the international relations between the Participants. 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.

This arrangement is concluded for a period of two years after which we will assess at least annually its effectiveness.

The European Commission and the EMEA should be obliged if FDA would acknowledge receipt of this letter and confirm that this letter and your reply constitute the arrangement set out above between our services.

We look forward to implementing this arrangement allowing for the sharing of non-public information and to continuing cooperative activities to further enhance the relationship between the FDA, the EMEA, and the European Commission, in the best interests of public and animal health.

Paul Weissenberg

Director, DG Enterprise
European Commission

Thomas Lönngren

Executive Director
European Agency for the
Evaluation of Medicinal
Products