DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

July 2, 2007

Dear Ms. Lalis:

The Food and Drug Administration (FDA) is pleased to cooperate with the European Commission (collectively "the Participants"), as part of cooperative law enforcement and cooperative regulatory activities, to facilitate the sharing of documents and/or information related to assuring the safety, quality, and efficacy, as appropriate, of medical devices. This information-sharing arrangement is intended, among other things, to help regulators on both sides to take informed decisions with regard to regulatory developments in their respective regions. 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. Advanced drafts of laws, regulations, guidance documents, guidelines, procedures and other technical documents available to the individual Participants related to medical devices.
2. Information on EU guidelines concerning market surveillance and vigilance, as well as clinical investigation and clinical evaluation, concerning medical devices..
3. Information in the framework of the Global Harmonization Task Force (GHTF) National Competent Authority Report Exchange System (NCAR).
4. Post-marketing data and information that could have an impact on the public health, such as vigilance data or information about impending regulatory actions.
5. Information on quality defect or product recalls of these products known by the FDA to have been manufactured or distributed in the EU, and vice versa.
6. Inspection reports and product sample test results describing the compliance of a medical device or its manufacturing with regulatory requirements.
7. Information on ongoing and emerging regulatory issues of health and safety in the field of medical devices in the U.S. or the EU, such as reprocessing of medical devices and nanotechnology.

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 European Commission has provided a statement to FDA affirming their authority and intent to maintain the confidentiality of non-public information provided by FDA to their officials or representatives under Article 4 of Regulation (EC) 1049/2001, and in particular paragraph 1(a) thereof, which protects non-public information from further disclosure. The European Commission agrees that "confidential commercial information" includes information referred to in the U.S. Freedom of Information Act (FOIA), 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 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 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 European Commission absent written confirmation by 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 FOIA, and in Regulation (EC) No. 1049/2001.

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

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 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 European Commission would sign a similar commitment if, during their visit to the European Commission, they are to have access to non-public information.

FDA will inform the European Commission promptly of any effort made by judicial or legislative mandate to obtain European Commission-provided non-public information from FDA. If such judicial or legislative mandate orders disclosure of European Commission-provided non-public information, FDA will take all appropriate legal measures in an effort to ensure that the information will be disclosed in a manner that protects the information from public disclosure.

Likewise, the European Commission will inform FDA promptly of any effort made by judicial or legislative mandate to obtain FDA-provided non-public information from the European Commission. If such judicial or legislative mandate orders disclosure of FDA-provided non-public information, the European Commission will take all appropriate legal measures in an effort to ensure that the information will be disclosed in a manner that protects the information from public disclosure.

The exchange of non-public information under this arrangement is reasonably necessary to facilitate cooperative law enforcement or cooperative regulatory activities between FDA, on the one hand, and the European Commission, on the other hand. All non-public information will be shared with the European Commission under this agreement in accordance with Title 21 of the Code of Federal Regulations § 20.89.

Each Participant will promptly inform the other of any changes to relevant laws, regulations, policies, or procedures that would affect the ability of the Participant to honor the understandings in this arrangement.

This cooperative arrangement is not intended to compromise any of the Participants' abilities to carry out their responsibilities.

This arrangement will commence July 2, 2007 for an initial period of five years, and remain in effect until July 2, 2012, 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 European Commission, will constitute our mutual consent 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 European Commission and the FDA.

Sincerely,

Andrew C. von Eschenbach, M.D.
Commissioner of Food and Drugs
United States Food and Drug Administration

VISITOR COMMITMENT TO PROTECT NON-PUBLIC INFORMATION AND ASSURANCE OF NO FINANCIAL INTEREST

I, _____, a representative of _____, am visiting the United States Food and Drug Administration ("FDA") for the purpose of _____. I certify that I have the authority to protect the confidentiality of the information I view on FDA premises. I agree to protect non-public information, including, but not limited to, confidential commercial or trade secret information, entrusted to me by:

1 storing the non-public information in the secured offices of FDA, and
2 granting access to the non-public 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 confidential commercial, trade secret, or other non-public information and notes pertinent thereto to FDA upon completion of my assignment, or upon FDA's request,
3 report in writing to an FDA official all incidents in which unauthorized persons might have gained access to non-public, including confidential commercial or trade secret, information entrusted to me, and
4 not disclose, publish, or share such non-public information without the written authorization of the sponsor of confidential commercial or trade secret information, or the express permission of FDA.

NO FINANCIAL INTEREST

Furthermore, I certify that I do not have any ownership or other financial interest in products regulated by _____ (name of Center(s) or Office).

I understand that unauthorized disclosure of non-public information may subject me to criminal penalties under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 331(j)), the Economic Espionage Act (18 U.S.C. § 1831-39), and the Trade Secrets Act (18 U.S.C. § 1905)).

_____ DATE:
SIGNATURE

_____
TYPED OR PRINTED NAME OF VISITOR:

WITNESSED:

_____ DATE:
SIGNATURE

_____
TYPED OR PRINTED NAME OF WITNESS: