EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Consumer goods
Director

Brussels, 2 July 2007
ENTR/F/3/LS/bl D(2007) 22465

Dear Dr. von Eschenbach,

I acknowledge receipt of your letter dated July 2, 2007 relating to exchange of information on medical devices. I confirm that we agree with the content, subject to the following:

This type of information may include information of a non-public nature; therefore, both sides agree, to the extent permitted by their respective laws, to keep any non-public information exchanged confidential.

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 or the European Commission.

This co-operation does not include classified information within the meaning of Commission Decision 2001/844.

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 interest of the EU or the European Commission's interest in the confidentiality of its proceedings. In some cases, exchange of information under this arrangement may be subject to prior authorization from the companies involved.

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

The European Commission affirms that it has 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 European

Dr Andrew C. Eschenbach, M.D.
Commissioner of Food and Drugs
United States Food and Drug Administration
5600 Fischers Lane
Rockville, MD 20857

Commission européenne, B-1049 Bruxelles / Europese Commissie, B-1049 Brussel - Belgium. Telephone: (32-2) 299 11 11.
Office: Brey 10/258. Telephone: direct line (32-2) 296.34.20. Fax: (32-2) 296.64.67.
E-mail : entr-cosm-med-devc.europa.eu

Commission understands 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 European Commission agrees that "confidential commercial information" includes information referred to in the U.S. Freedom of Information Act, 5 U.S.C. § 552(b)(4), and in Regulation (EC) No. 1049/2001.

We look forward to implementing this arrangement and to continuing cooperative activities to further enhance the relationship between the FDA and the European Commission in the best interests of our societies.

Yours sincerely,

Georgette Lalis