

Page 3 – Mr. Paul Weissenberg  
Mr. Thomas Lönngren

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.