

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 (EMA). The participants concluded this exchange of letters on September 12, 2003. These letters express the intentions of FDA, the European Commission, and EMA 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.

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: December 18, 2003

Jeffrey Shuren,

Assistant Commissioner for Policy.

[INSERT AGREEMENT]

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

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