From: A Message from the Commissioner
Sent: Friday, March 13, 2009 3:52 PM
To: FDA-Wide
Subject: Protecting Confidential Information

FDA is committed to the principles of open Government and transparency, as outlined in the Presidential Memoranda of January 21, 2009. At the same time, FDA must comply with its obligations to keep certain information in its possession confidential. The statutes, regulations, and policies under which FDA operates require that certain information in the agency's possession be kept confidential except in certain, often narrow, circumstances where disclosure is authorized by law and all procedural safeguards (such as management concurrence) have been satisfied. Among the laws governing disclosure or requiring confidentiality are the Federal Food, Drug, and Cosmetic Act, the Freedom of Information Act (FOIA), the Trade Secrets Act, and the Privacy Act, as well as FDA's implementing regulations. Violation of these provisions can result in disciplinary sanctions and/or individual criminal liability. Improper disclosure could also result in FDA being sued for damages.

It is imperative that all of us ensure that we are vigilant in fulfilling our critical responsibility to safeguard information entrusted to the agency, and I know that I can count on you to comply with all applicable confidentiality requirements. Determinations regarding disclosure are to be made through the designated FOIA/Privacy Act contacts in your organization following agency procedures.

The information in question generally falls under, but is not limited to, one of the following categories:

1. Trade Secrets. A trade secret is a commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process. Examples of trade secrets include materials used in manufacture which are not immediately identifiable, manufacturing processes, quality control procedures, sterilization techniques, and formulas that are not on the product labeling. Among other documents, trade secrets are frequently found in Establishment Inspection Reports (EIRs) and pre-market applications.

2. Confidential Commercial Information (CCI). Confidential commercial information is valuable data or information used in one's business that (a) if voluntarily submitted to FDA, is of the type customarily not disclosed to the public by the person to whom the information belongs, or (b) if not voluntarily submitted to FDA (e.g., if required for certain product approvals), is information which, if disclosed by FDA, would be likely to cause substantial harm to the competitive position of the person to whom the information belongs or would impair the agency's ability to obtain similar information in the future. Examples of CCI include safety and effectiveness and other research data, sales statistics, customer and supplier lists, profit and loss data, overhead and operating costs, and other financial information. CCI is often found in the same kinds of documents that contain trade secrets.

3. Personal Privacy Information. Personal privacy information is information the disclosure of which would constitute a clearly unwarranted invasion of privacy. Examples of such information can include the names of patients (or other personal identifying information about

patients) in clinical trials, the names of persons, including physicians, who voluntarily submit adverse experience reports or consumer complaints, and the vast majority of information in personnel files (including social security numbers and other personal identifiers, home addresses, bank account numbers, etc.). It also includes information protected under the Privacy Act.

4. Privileged Intra-agency and Inter-agency Documents. This covers, for example, internal memoranda, letters, and e-mail to and from employees within FDA (intra-agency) and to and from FDA and other Government agencies (inter-agency). The most common privileges include (a) the deliberative process privilege, which protects the pre-decisional advice, opinions, and recommendations of agency employees; (b) the attorney-client privilege, which protects confidential communications between FDA and its attorneys related to a legal matter for which FDA has sought legal advice; and (c) the attorney-work product privilege, which protects documents and other memoranda prepared by an attorney for FDA in contemplation of litigation. Examples of documents that might contain this kind of information include drafts of policy-making documents, draft notices of proposed and final rules, drafts of other Federal Register documents, recommendations to take (or not to take) some regulatory or enforcement action, requests for legal opinions and the opinions themselves, etc.

5. Law Enforcement Records and Information. This covers a wide assortment of information that is compiled for law enforcement purposes if disclosure of the information, among other things, (a) could reasonably be expected to interfere with enforcement proceedings, (b) could reasonably be expected to disclose the identity of a confidential source, (c) could reasonably be expected to constitute an unwarranted invasion of personal privacy, or (d) would disclose law enforcement procedures and techniques if such disclosure could reasonably be expected to risk circumvention of the law. Examples of such documents include Establishment Inspection Reports (EIRs), memoranda, and other documents relating to an investigation. Certain of these documents may be disclosed once the investigation or matter is closed.

For more information about these and other categories of information that we must keep confidential, please refer to Staff Manual Guide 2280.10, Protection of Non-Public Information (NPI) available at http://inside.fda.gov/PolicyProcedures/StaffManualGuide/VolumeIIIGeneralAdministration/UCM007444.html. In addition, the FY 2009 ISSO Online Computer Security Awareness Training course includes a module describing FDA's security policies and procedures regarding the protection of non-public information and is available at http://inside.fda.gov/it/ITSecurity/SecurityOverview/UCM005415.html.

Questions about disclosure should be referred to the appropriate FOIA/Privacy Act contact in your organization.

Frank M. Torti, M.D., MPH
Acting Commissioner of Food and Drugs