

## B. Principles and Procedures for the Exchange of Information That is Not Publicly Available

FDA and CDC agree that the following principles and procedures will govern the exchange of nonpublic information between the two agencies.

Although there is no legal requirement that FDA and CDC exchange information in all cases, FDA and CDC agree that there should be a presumption in favor of full and free sharing of information between FDA and CDC. As sister public health agencies within the Department of Health and Human Services, there are no legal prohibitions that preclude FDA or CDC from sharing with each other most agency records in the possession of either agency. Both agencies recognize and acknowledge, however, that it is essential that any confidential information that is shared between FDA and CDC must be protected from unauthorized public disclosure. See e.g., 21 U.S.C. sec. 331(j); 18 U.S.C. section 1905; 21 C.F.R. Parts 20 and 21; 42 C.F.R. Parts 5 and 5b, and 42 U.S.C. section 301(d). Safeguards are important to protect the interests of, among others, owners and submitters of trade secrets and confidential commercial information; patient identities and other personal privacy information; privileged and/or pre-decisional agency records; and information protected for national security reasons. Such safeguards also help guarantee FDA's and CDC's compliance with applicable laws and regulations.

To facilitate the sharing of information with each other, it is necessary that FDA and CDC implement procedures to ensure, at a minimum, that such sharing of information is indeed appropriate and that the recipient agency guards the confidentiality of all information received.<sup>1</sup> There are separate procedures, as described below, for routine requests for information and for emergency requests. It is incumbent upon both agencies to respond to requests for information in a timely manner. Any unauthorized disclosure of shared confidential information by the agency receiving the information shall be the responsibility of that agency.

### 1. Routine Requests for Information

a. The requesting agency must demonstrate, in writing, why it is necessary for it to obtain the requested information. This demonstration should consist of a summary that describes in detail the information requested (to facilitate identification of relevant records) and a brief statement of the purpose for which the information is needed. This request shall state which internal agency offices and/or individuals requested the information. A model request letter is attached.

b. The agency receiving the request for information shall, based upon the

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<sup>1</sup> It is assumed that each agency has implemented or will implement all data and information security requirements and has implemented or will implement, to the extent necessary and practicable, all data and information security recommendations.