

sufficiency of the need-to-know demonstration described in section III B 1a above, determine whether it is appropriate to share the requested information with the requesting agency. The need-to-know threshold is a low one. As stated above, there is a presumption in favor of information exchange between FDA and CDC. An agency should only decide not to share information in response to a request if it has credible information and a reasonable belief that the requesting agency may not be able to comply with applicable laws or regulations governing the protection of non-public information or with the principles or procedures set forth in this MOU. If an agency decides that it is not appropriate to share information with the requesting agency, it shall describe to the requesting agency the reasons for such decision.

c. The requesting agency agrees that it shall comply with the following conditions:

- The requesting agency shall limit the dissemination of shared information it receives to internal agency offices and/or individuals that have been identified in its written request and/or have a need-to-know. The agency official who signs the request letter will be responsible for ensuring that there are no other recipients of the information.

- The requesting agency shall agree in writing not to publicly disclose any shared information in any manner including publications and public meetings. If the requesting agency wishes to disclose shared information, including information that it believes is publicly releasable, it shall first request and obtain the written permission of the agency that has shared the information. If the requesting agency receives a Freedom of Information Act (FOIA) request for the shared information, it will refer the request to the information-sharing agency for it to respond directly to the requester regarding the releasability of the information. In such cases, the agency making the referral will notify the requester that a referral has been made and that a response will issue directly from the other agency.

- The agency that shares information with the requesting agency shall include a transmittal letter, along with any agency records exchanged. The transmittal letter shall indicate the type of information (e.g., confidential commercial information, personal privacy, or pre-decisional). A model transmittal letter is attached.

- The requesting agency shall promptly notify the appropriate office of the information-sharing agency when there is any attempt to obtain shared information by compulsory process, including but not limited to, a FOIA request, subpoena, discovery request, or litigation complaint or motion.

- The requesting agency shall notify the information-sharing agency before