

[Model Transmittal letter from CDC to FDA]

This letter accompanies agency records that the Center for Disease Control and Prevention (CDC) is sharing with the Food and Drug Administration (FDA) in response to FDA's request, dated _____. These agency records contain one or more of the following categories of non-public information, including information the public disclosure of which may be prohibited by law:

[CDC checks applicable numbers below]

- ___ trade secrets;
- ___ confidential commercial or financial information;
- ___ information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;
- ___ information subject to the Privacy Act;
- ___ intra-agency records;
- ___ records or information compiled for law enforcement purposes; or
- ___ information protected for national security reasons.

FDA shall notify the appropriate office of the information-sharing agency if there are any attempts to obtain shared information by compulsory process, including but not limited to, Freedom of Information Act requests, subpoenas, discovery requests, and litigation complaints or motions.

FDA shall notify the information-sharing agency before complying with any judicial order that compels the release of such information so that FDA and/or CDC may take appropriate measures, including filing a motion with the court or an appeal.

FDA has agreed, by this letter or e-mail and by a signed request letter dated _____, not to publicly disclose the above-described information without prior written permission of CDC. FDA acknowledges that applicable laws and regulations may prohibit the disclosure of such information. See, e.g., 21 U.S.C. §331(j); 18 U.S.C. §1905, 21 C.F.R. Parts 20 and 21, 42 C.F.R. Parts 5 and 5b, and 42 U.S.C. §301(d). FDA also agrees to comply with the principles and procedures set forth in the Memorandum of Understanding between FDA and CDC, cite.