

[Model Transmittal letter from FDA to CDC]

This letter accompanies agency records that the Food and Drug Administration (FDA) is sharing with the Center for Disease Control and Prevention (CDC) in response to CDC'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:

[FDA 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.

CDC 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.

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

CDC 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 FDA.

CDC 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, and 21 CFR Parts 20 and 21, 42 C.F.R. Parts 5 and 5b, and 42 U.S.C. §301(d). CDC also agrees to comply with the principles and procedures set forth in the Memorandum of Understanding between FDA and CDC, *cite*.

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**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

Food and Drug Administration

[Docket No. 2003D-0504]

**Medical Devices; Guidance for
Industry and FDA Staff; Bundling
Multiple Devices or Multiple
Indications in a Single Submission;
Availability**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the

availability of the guidance entitled "Bundling Multiple Devices or Multiple Indications in a Single Submission." This guidance describes FDA's policy on bundling multiple devices or multiple indications in a single premarket submission. Under the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), the bundling policy takes on additional importance because of the fees that are now associated with certain submissions as well as the performance goals the agency has committed to meet. The guidance is being issued as final for immediate implementation with an