[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*.

[FR Doc. 03–29497 Filed 11–25–03; 8:45 am]
BILLING CODE 4160–01–C

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

opportunity for public comment on the guidance after issuance.

DATES: Submit written or electronic comments on this guidance at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Bundling Multiple Devices or Multiple Indications in a Single Submission'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

For device evaluation issues: Bob Gatling, Office of Device Evaluation, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190, ext. 140.

For in vitro diagnostic device issues: Sousan Altaie, Office of In Vitro Diagnostic Device Evaluation and Safety, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3084, ext. 145.

For biologics issues: Sheryl Kochman, Center for Biologics Evaluation and Research (HFM–390), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6123

SUPPLEMENTARY INFORMATION:

I. Background

MDUFMA amended the Federal Food, Drug, and Cosmetic Act by authorizing FDA to collect user fees for certain premarket submissions (premarket approval applications, premarket reports, supplements, premarket notifications, biologics license applications, and efficacy supplements) received on or after October 1, 2002. A letter from the Secretary of Health and Human Services to Congress that accompanies the user fee legislation sets forth performance goals and policy and procedural provisions. One of these provisions is entitled ''Bundling Policy'' and states that FDA will consider, in consultation with its stakeholders, when bundling multiple devices in a single submission may be appropriate. *(http://www.fda.gov/cdrh/mdufma/pgoals.html)*.

This guidance describes FDA's policy on bundling multiple devices or multiple indications in a single premarket submission and is intended to help FDA staff and industry determine when bundling is appropriate. In developing this guidance, the agency has considered comments on the topic that were submitted to the public docket on MDUFMA Implementation (Docket No. 02N–0534). FDA has also included in the guidance many of the examples provided by stakeholders.

II. Significance of Guidance

This guidance document supersedes Section V, ''Bundling Multiple Devices in a Single Application'' of the February 2003 guidance entitled, ''Assessing User Fees: PMA Supplement Definitions, Modular PMA Fees, BLA and Efficacy Supplement Definitions, Bundling Multiple Devices in a Single Application, and Fees for Combination Products; Guidance for Industry and FDA.'' FDA announced the availability of that guidance in the **Federal Register** of February 25, 2003 (68 FR 8773). As discussed above, FDA reviewed the comments received on the issue of bundling. FDA also invites comments on this guidance document (see section V of this document).

This guidance document is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on bundling multiple devices or multiple indications in a single premarket submission. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call one of the numbers listed above or on the title page of the guidance document.

III. Electronic Access

To receive ''Bundling Multiple Devices or Multiple Indications in a Single Submission'' by fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1215) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance document may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Dockets Management Branch Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance document contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 USC 3501–3520) (the PRA). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E), OMB No. 0910–0120 and premarket approval applications (21 CFR part 814), OMB No. 0910–0231.

V. Comments

Interested persons may submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, written or electronic comments regarding this document. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit two hard copies of any mailed comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the Dockets

Management Branch between 9 a.m. and 4 p.m., Monday through Friday. FDA will review any comments we receive and revise the guidance document when appropriate.

Dated: November 19, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–29461 Filed 11–25–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998D–0173]

Guidance for Industry and FDA Staff: Expedited Review of Premarket Submissions for Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Expedited Review of Premarket Submissions for Devices.'' This guidance describes how the agency is applying the statutory criteria and the additional criteria identified in a letter accompanying the user fee legislation to meet the new performance goals for expedited premarket approval applications (PMAs). This guidance also describes FDA's expedited review procedures for premarket notification submissions (510(k)s), product development protocols (PDPs), and *de novo* classification actions. This guidance document is immediately in effect, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5'' diskette of the guidance document entitled ''Expedited Review of Premarket Submissions for Devices'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

For questions regarding PMAs: Thinh Nguyen, Center for Devices and Radiological Health (HFZ–402), 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

For questions regarding 510(k)s, including the evaluation of automatic class III designation: Heather Rosecrans, Center for Devices and Radiological Health (HFZ–402), 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

For questions regarding devices regulated by the Center for Biologics Evaluation and Research: Sayah Nedjar, Center for Biologics Evaluation and Research (HFM–380), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3524.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 31, 1998 (63 FR 15427), FDA issued a guidance entitled ''PMA/510(k) Expedited Review Guidance for Industry and the Center for Devices and Radiological Health (CDRH) Staff'' in which the agency outlined its interpretation of the statutory criteria for expedited review of PMAs. No comments were received on the guidance.

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107–250), was signed into law on October 26, 2002. Performance goals for expedited PMAs were referenced in the statute and apply to such applications when newly identified criteria are met by the applicant (*http://www.fda.gov/cdrh/mdufma/pgoals.html*). The new guidance entitled ''Expedited Review of Premarket Submissions for Devices'' supersedes and replaces the 1998 guidance document and explains the procedures that FDA intends to use to review and track expedited PMA applications against the MDUFMA performance goals when the PMA applicant meets the additional criteria. The new guidance also explains the procedures that FDA plans to use to expedite the review of PDPs, 510(k)s, and *de novo* classification actions.

Because the agency had to implement its program for meeting the expedited review performance goals as soon as the new law became effective. FDA has determined, under §10.115(g)(2) (21 CFR 10.115(g)(2)), that it was not feasible to obtain comments before issuing this guidance. Therefore, in accordance with FDA's GGP procedures, FDA is issuing this as a level 1 guidance that is immediately in effect and will accept comments on the guidance at any time.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (§10.115). The guidance represents the agency's current thinking on procedures for expedited review of PMAs, given the enhanced PMA performance goals for expedited applications. The guidance also discusses the expedited review procedures for 510(k)s, PDPs, and *de novo* classification actions. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

To receive ''Expedited Review of Premarket Submissions for Devices'' by fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (108) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*.