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]

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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*.

Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance 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 U.S.C. 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 for premarket approval applications (21 CFR part 814, OMB control number 0910–0231) and the regulations for premarket notification submissions (21 CFR part 807, OMB control number 0910–0120).

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments* or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Data System for Organ Procurement and Transplantation Network and Associated Forms (OMB No. 0915–0157): Revision

Section 372 of the Public Health Service (PHS) Act requires that the Secretary, by contract, provide for the establishment and operation of an Organ Procurement and Transplantation Network (OPTN). The OPTN, among other responsibilities, operates and maintains a national waiting list of individuals requiring organ transplants, maintains a computerized system for matching donor organs with transplant candidates on the waiting list, and operates a 24-hour telephone service to facilitate matching organs with individuals included in the list.

Data for the OPTN data system are collected from transplant hospitals, organ procurement organizations, and tissue-typing laboratories. The information is used to match donor organs with recipients, to monitor compliance of member organizations with OPTN rules and requirements, and to report periodically on the clinical and scientific status of organ donation and transplantation in this country. Data are used in the development and revision of OPTN rules and requirements, operating procedures, and standards of quality for organ acquisition and preservation, some of which have provided the foundation for development of Federal regulations. The practical utility of the data collection is further enhanced by requirements that the OPTN data must be made available without restriction for use by OPTN members, the Scientific Registry of Transplant Recipients, the Department of Health and Human Services, and others for evaluation, research, patient information, and other important purposes.

Revisions in the 28 data collection forms and addition of 2 survey instruments are intended to clarify existing questions, to provide additional detail and categories to avoid confusion and be more inclusive, to remove obsolete data, and to comply with requests for more complete and precise data.

ESTIMATES OF ANNUALIZED HOUR BURDEN

Form	Number of respondents	Responses per respondents	Total responses	Hours per response	Total burden hours
Deceased Donor Registration	59	173	10,207	0.3	3,062.10
Death referral data	59	12	708	10	7,080.00
Living Donor Registration	692	10	6,920	0.2	1,384.00
Living Donor Followup	692	19	13,148	0.1	1,314.80
Donor Histocompatibility	152	87	13,224	0.1	1,322.40
Recipient Histocompatibility	152	163	24,776	0.1	2,477.60
Heart Candidate Registration	139	23	3,197	0.3	959.10
Lung Candidate Registration	70	28	1,960	0.3	588.00
Heart/Lung Candidate Registration	72	1	72	0.3	21.60
Thoracic Registration	139	24	3,336	0.3	1,000.80
Thoracic Followup	139	174	24,186	0.2	4,837.20
Kidney Candidate Registration	247	109	26,923	0.2	5,384.60
Kidney Registration	247	65	16,055	0.3	4,816.50
Kidney Followup *	247	493	121,771	0.2	24,354.20