applications must maintain these records.

PMAs have been required since 1976, and there are 1,128 active PMAs that could be subject to these requirements, based on actual FDA data. Each study has approximately 200 subjects, and at an average of 5 minutes per subject, there is a total burden per study of 1,000 minutes, or 17 hours. The aggregate burden for all 1,128 holders of approved original PMAs, therefore, is 19,176 hours (1,127 approved PMAs with clinical data x 17 hours per PMA).

The applicant determines which records should be maintained during product development to document and/or substantiate the device's safety and effectiveness. Records required by the current good manufacturing practices for medical devices regulation (part 820) may be relevant to a PMA review and may be submitted as part of an application. In individual instances, records may be required as conditions of approval to ensure the device's continuing safety and effectiveness.

Dated: September 11, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–18222 Filed 9–14–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0347]

Draft Guidance for Industry, Clinical Laboratories, and Food and Drug Administration Staff on In Vitro Diagnostic Multivariate Index Assays; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until October 17, 2007, the comment period for ''Draft Guidance for Industry, Clinical Laboratories, and FDA Staff on In Vitro Diagnostic Multivariate Index Assays'' published in the **Federal Register** of July 26, 2007 (72 FR 41081). That guidance was a revised version of the original draft, which was published on September 7, 2006, with a 90-day comment period that was extended to 180 days. In addition, FDA held a public meeting on the draft guidance in February 2006. FDA is reopening the comment period on the revised draft to allow sufficient time for stakeholder comment.

DATES: Submit written or electronic comments by October 17, 2007.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Draft Guidance for industry, Clinical Laboratories, and FDA Staff on In Vitro Diagnostic Multivariate Index Assays'' to the Division of Small Manufacturers, International,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 one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft 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* or *http://www.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Courtney Harper, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0694.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 26, 2007 (72 FR 41081), FDA published a notice of availability of a revised draft guidance, ''Draft Guidance for Industry, Clinical Laboratories, and FDA Staff on In Vitro Diagnostic Multivariate Index Assays'' with a 30-day comment period. The In Vitro Diagnostic Multivariate Index Assays (IVDMIAs) guidance document has been the subject of attention, comment, and public discussion for almost a year. The original draft was published on September 7, 2006, with a 90-day comment period. In response to requests for further opportunity to comment, FDA extended the comment period to 180 days and held a public meeting on the guidance document. The second draft, which was published July 26, 2007, incorporated many of the suggested comments on the first draft. Among other things, the second draft simplified the definition of IVDMIAs, and provided a variety of specific examples to assist sponsors in understanding the definition. In light of the opportunities for comment on the first draft, we had originally set a 30-day period for comments on the second draft. The initial comment period closed on August 27, 2007. However, at the request of in vitro diagnostic device stakeholders, the agency has decided to reopen the comment period for an additional 30 days on the ''Draft Guidance for Industry, Clinical Laboratories, and FDA Staff on In Vitro Diagnostic Multivariate Index Assays.''

This draft guidance is intended to provide clarification on FDA's approach to regulation of IVDMIAs.

II. Request for Comments

Following publication of the July 26, 2007, ''Draft Guidance for Industry, Clinical Laboratories, and FDA Staff on In Vitro Diagnostic Multivariate Index Assays,'' FDA received requests to allow interested persons additional time to comment. The requesters asserted that the time period of 30 days was insufficient to respond fully to FDA's specific requests for comments and to allow potential respondents to thoroughly evaluate and address pertinent issues.

III. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized will represent the agency's current thinking on IVDMIAs. 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 statute and regulations.

IV. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To received ''Draft Guidance for Industry, Clinical Laboratories, and FDA Staff on In Vitro Diagnostic Multivariate Index Assays,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1610 to identify the guidance you are requesting.

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*.

V. How to Submit 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 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: September 11, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–18221 Filed 9–14–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Data System for Organ Procurement and Transplantation Network (42 CFR Part 121, OMB No. 0915–0184): Extension

The operation of the Organ Procurement and Transplantation Network (OPTN) necessitates certain recordkeeping and reporting requirements in order to perform the functions related to organ transplantation under contract to HHS. This is a request for an extension of the current recordkeeping and reporting requirements associated with the OPTN. These data will be used by HRSA in monitoring the contracts for the OPTN and the Scientific Registry of Transplant Recipients (SRTR) and in carrying out other statutory responsibilities. Information is needed to match donor organs with recipients, to monitor compliance of member organizations with OPTN rules and requirements, to ensure that all qualified entities are accepted for membership in the OPTN, and to ensure patient safety.

ESTIMATED ANNUAL REPORTING AND RECORD KEEPING BURDEN

Section and activity	Number of respondents	Responses per respondents	Total responses	Hours per response	Total burden hours
121.3(b)(2)—OPTN membership and application requirements for OPOs, hospitals, and histocompatibility laboratories	40	3	120	15	1, 800
121.3(b)(4)—Appeal for OPTN membership	2	1	2	3	6
121.6(c) (Reporting)—Submitting criteria for organ acceptance	900	1	900	0.5	450
121.6(c) (Disclosure)—Sending criteria to OPOs	900	1	900	0.5	450
121.7(b)(4)—Reasons for Refusal	900	38	34,200	0.5	17,100
121.7(e) —Transplant to prevent organ wastage	260	1.5	390	0.5	195
121.9(b)—Designated Transplant Program Requirements	10	1	10	5.0	50
121.9(d)—Appeal for designation	2	1	2	6	12
Total	954		36,524		20,063

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974. Please direct all correspondence to the ''attention of the desk officer for HRSA.''

Dated: September 10, 2007.

Alexandra Huttinger,

Acting Director, Division of Policy Review and Coordination.

[FR Doc. E7–18220 Filed 9–14–07; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the OMB for review under the Paperwork Reduction Act of 1995:

Proposed Project: The Nurse Faculty Loan Program (NFLP): Annual Operating Report (AOR) Form—NEW

The Annual Operating Report (AOR) provides information on the Nurse Faculty Loan Program (NFLP) funded loan activities. Under Title VIII of the Public Health Service Act, as amended by Public Law 107–205, Section 846A, the Secretary of Health and Human Services (HHS) enters into an agreement with a school of nursing to establish and operate the NFLP fund. HHS makes an