Background and Brief Description

This project involves formative research to inform the development of the HIV Testing Social Marketing Campaign for African American Heterosexual Men, a CDC-sponsored social marketing campaign aimed at increasing HIV testing rates among young, single, African American men. The study entails conducting focus groups and interviews with a sample of single African American heterosexual men, ages 18 to 44, with less than 4 years of college education to: (1) Explore participants' knowledge, attitudes and beliefs about HIV and HIV testing to inform the development of campaign messages; (2) identify the most motivating approach, supporting data, and key messages for materials development; (3) test creative concepts, potential campaign themes, logos and names; and (4) test creative materials developed based on the findings from the previous phases of the research. Findings from this study will be used by CDC and its partners to inform current and future program activities.

We expect 153 participants to be screened for eligibility annually. Of the 153 participants who are screened, we anticipate that 72 will participate. The 72 participants will be divided; 36 participating in focus groups and 36 participating in interviews. Additionally, all focus group and interview participants will complete a short ''Paper and Pencil'' questionnaire. This is a burden hour reduction from the 60 Day **Federal Register** Notice which estimated the annual number of respondents at 306, with 153 participating; 81 in focus groups and 72 in interviews. There are no costs to the respondents other than their time. The total estimated annual burden hours are 146.

ESTIMATED ANNUALIZED BURDEN HOURS AND BURDEN TABLE

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Screener	153	1	10/60
Focus Group	36	1	2
Interview	36	1	1
Paper and Pencil Survey	72	1	10/60

Dated: September 7, 2007.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E7–18231 Filed 9–14–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0231]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Premarket Approval of Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by October 17, 2007.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0073. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance:

Premarket Approval of Medical Devices—21 CFR Part 814 and Food and Drug Administration Modernization Act Sections 201, 202, 205, 208, and 209 (OMB Control Number 0910–0231)—Extension

Section 515 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e) sets forth the requirements for premarket approval of certain class III medical devices. Class III devices are either preamendments devices that have been classified into class III, or postamendments devices which are not substantially equivalent to a preamendments device, or transitional devices. Class III devices are devices such as implants, life sustaining or life supporting devices, devices that are of substantial importance in preventing impairment of human health, and devices that otherwise present a potentially unreasonable risk of illness or injury. Most premarket approval application (PMAs) are for postamendments class III devices.

Under section 515 of the act, an application must contain certain specific information, including full reports of all information concerning investigations showing whether the device is reasonably safe and effective. The application should also include a statement of components, ingredients, and properties of the principles of operation for such a device. In addition, the application should also include a full description of the methods used in, and the facilities and controls used for, the manufacture and processing of the device and labeling specimens. The implementing regulations, contained in part 814 (21 CFR part 814), further specify the contents of a PMA for a class III medical device and the criteria FDA sets forth in approving, denying, or withdrawing approval of a PMA as well as supplements to PMAs. The purpose of these regulations is to establish an efficient and thorough procedure for FDA's review of PMAs and supplements to PMAs for certain class III (premarket approval), medical devices. The regulations under part 814 facilitate the approval of PMAs and supplements to PMAs for devices that have been shown to be reasonably safe and effective and otherwise meet the statutory criteria for approval. The regulations also ensure

the disapproval of PMAs and supplements to PMAs for devices that have not been shown to be reasonably safe and effective and that do not otherwise meet the statutory criteria for approval.

The Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115) was enacted on November 21, 1997, to implement revisions to the act by streamlining the process of bringing safe and effective drugs, medical devices, and other therapies to the U.S. market. Several FDAMA provisions affect the PMA process, such as section 515(d)(6) of the act. This section provided that PMA supplements were required for all device changes that affect safety and effectiveness of a device unless such changes are modifications to manufacturing procedures or method of manufacture. This type of manufacturing change now requires a 30-day notice, or where FDA finds such notice inadequate, a 135-day PMA supplement.

To make the PMA process more efficient, in the past several years FDA has done the following: (1) Made changes to the PMA program based on comments received, (2) complied with changes to the program mandated by FDAMA and Medical Device User Fee Modernization Act (Public Law 107–250), and (3) worked toward completion of its PMA reinvention efforts.

Respondents to this information collection are persons filing a PMA application or a PMA supplement with FDA for approval of certain class III medical devices. Part 814 defines a person as any individual, partnership, corporation, association, scientific or academic establishment, Government agency or organizational unit, or other legal entity. These respondents include entities meeting the definition of manufacturers, such as manufacturers of commercial medical devices in distribution prior to May 28, 1976 (the enactment date of the Medical Device Amendments). In addition, hospitals that reuse single use devices (SUDs) are also included in the definition of manufacturers. It is expected that FDA will receive four PMA applications from hospitals that remanufacture SUDs annually. This figure has been included in table 1 of this document, as part of the reporting burden in § 814.15.

In the **Federal Register** of June 28, 2007 (72 FR 35494), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
21 CFR					
814.15(b)	10	1	10	2	20
814.20(a) through (c) and (e)	48	1	48	668	32,064
814.37	48	1	48	167	8,016
814.39(a)	460	1	460	60	27,600
814.39(d)	70	1	70	6	420
814.39(f)	254	1	254	16	4,064
814.82(a)(9)	34	1	34	135	4,590
814.84(b)	34	1	34	10	340
FDAMA					
201—Agreement Meeting	3	1	3	50	150
202—Expedited Reviews	7	1	7	10	70
205—Determination Meeting	5	1	5	50	250
208—Classification Panel Meetings	19	1	19	30	570
209—100-day Meeting	36	1	36	10	360
Total	1,028	13	1,028	1,214	78,514

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
814(a)(5) and (a)(6)	1,128	1	1,128	17	19,176

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The industry-wide burden estimate for PMAs is based on an FDA actual average fiscal year (FY) annual rate of receipt of 48 PMA original applications, 530 PMA supplements, and 254 30-day notices using FY 2002 through FY 2006 data. The burden data for PMAs is based on data provided by manufacturers by device type and cost element in an earlier study. The specific burden elements for which FDA has data are as follows:

- Clinical investigations: 67 percent of total burden estimate;
- Submission of additional data or information to FDA during a PMA review: 12 percent;
- Additional device development cost (e.g., testing): 10 percent; and
- PMA and PMA supplement preparation and submissions, and development of manufacturing and controls data: 11 percent.

Reporting Burden

The reporting burden can be broken out by certain sections of the PMA regulation as follows:

§ 814.15—Research Conducted Outside the United States

Approximately 20 percent of the clinical studies submitted in support of a PMA application are conducted outside the United States. Each study should be performed in accordance with the ''Declaration of Helsinki'' or the laws and regulations of the country in which the study was conducted. If the study was conducted in accordance with the laws of the country, the PMA applicant is required to explain to FDA in detail the differences between the laws of the country and the ''Declaration of Helsinki.'' Based on the number of PMAs received that contained studies from overseas, FDA estimates that the burden estimate necessary to meet this requirement is 20 hours.

§ 814.20(a) through (c) and (e)—Application

The majority of the 32,064 hourly burden estimate is due in part to this requirement. Included in this requirement are the conduct of laboratory and clinical trials as well as the analysis, review, and physical preparation of the PMA application. FDA estimates that 48 manufacturers, including hospital re-manufacturers of single use devices (SUDs), will be affected by these requirements which are based on the actual average of FDA receipt of new PMA applications in FY 2002 through 2006. FDA's estimate of the hours per response (668), was derived through FDA's experience and consultation with industry and trade associations. In addition, FDA also based its estimate on the results of an earlier study which accounts for the bulk of the hourly burden for this requirement, identified by manufacturers.

§ 814.37—PMA Amendments and Resubmitted PMAs

As part of the review process, FDA often requests PMA applicant to submit additional information regarding the device necessary for FDA to file the PMA or to complete its review and make a final decision. The PMA applicant may, also on their own initiative, submit additional information to FDA during the review process. These amendments contain information ranging from additional test results, re-analysis of the original data set to revised device labeling. Almost all PMAs received by the Agency have amendments submitted during the review process. FDA estimates that 8016 burden hours are necessary to satisfy this requirement.

§ 814.39(a)—PMA Supplements

FDA believes that the amendments mandated by FDAMA for § 814.39(f), permitting the submission of the 30-day notices in lieu of regular PMA supplements, will result in an approximate 20 percent reduction in the total number of hours as compared to regular PMA supplements. As a result, FDA estimates that 27,600 hours of burden are needed to complete the requirements for regular PMA supplements.

§ 814.39(d)—Special PMA Supplements—Changes Being Effected

This type of supplements is intended to enhance the safety of the device or the safe use of the device. The number of PMA supplements received that fit this category averaged 70 per year based on the numbers received from FY 2002 through FY 2006. Because of the minimal data required to be included in this type of supplement, FDA estimates that the burden hours necessary to satisfy this requirement are 420 hours.

§ 814.39(f)—30-day Notice

Under section 515(d) of the act, modifications to manufacturing procedures or methods of manufacture that affect the safety and effectiveness of a device subject to an approved PMA do not require submission of a PMA supplement under § 814.39(a) and are eligible to be the subject of a 30-day notice. A 30-day notice shall describe in detail the change, summarize the data or information supporting the change, and state that the change has been made in accordance with the requirements of part 820 (21 CFR part 820). The manufacturer may distribute the device 30 days after the date on which FDA receives the 30-day notice, unless FDA notifies the applicant within 30 days from receipt of the notice that it is not adequate. FDA estimates the burden to satisfy this requirement is 4,064 hours.

§ 814.82(a)(9)—Postapproval Requirements

Postapproval requirements concern approved PMAs that were not reclassified and require a periodic report. After approval, all PMAs require a submission of an annual report. On average, approximately half of the submitted PMAs (34), require associated postapproval studies, i.e., followup of patients used in clinical trials to support the PMA or additional preclinical information, that is labor-intensive to compile and complete; the remaining PMAs require minimal information. Based on experience and consultation with industry, FDA has estimated that preparation of reports and information required by this section requires 4,590 hours.

§ 814.84(b)—Reports

Postapproval requirements described in § 814.82(a)(7) require submission of an annual report for each approved PMA. FDA estimates that respondents will average about 10 hours in preparing their reports to meet this requirement. This estimate is based on FDA's experience and consultation with industry. Thus, FDA estimates that the periodic reporting burden required by this section will take 340 hours.

Statutory Reporting Burden Estimate (FDAMA)

The total statutory reporting burden under the requirements of FDAMA sections 201, 202, 205, 208, and 209 is estimated to be 1,400 hours. This burden estimate was based on actual real FDA data tracked from January 1, 1998, to the present, and an estimate was also derived to forecast future expectations with regard to this statutory data.

§ 814.82(a)(5) and (a)(6)—Recordkeeping

The recordkeeping burden under this section requires the maintenance of records, used to trace patients, and the organization and indexing of records into identifiable files to ensure the device's continued safety and effectiveness. These records are required only of those manufacturers who have an approved PMA and who had original clinical research in support of that PMA. For a typical year's submissions, 70 percent of the PMAs are eventually approved with 75 percent of these having original clinical trial data. Therefore, approximately 34 PMAs a year (48 annual submissions x 70 percent), would be subject to these requirements. Also, because the requirements apply to all active PMAs, all holders of an active PMA

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