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- The winning app must be available for free, to all users, until December 31, 2013. This includes hosting and maintaining the Web service in a scalable format, providing technical support with bug fixes, and so on.

**Authority:** 15 U.S.C. 3719.

Dated: July 17, 2012.

**Farzad Mostashari,**

*National Coordinator for Health Information Technology.*

[FR Doc. 2012-18593 Filed 7-30-12; 8:45 am]

**BILLING CODE 4150-45-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Delegation of Authority; International Cooperation

Notice is hereby given that I have delegated to the Director, Center for Global Health, Centers for Disease Control and Prevention (CDC) without authority to redelegate, the authority vested in the Director, CDC, under section 307 of the Public Health Service (PHS) Act (42 U.S.C. 242(1)).

This delegation became effective upon date of signature. I hereby affirm and ratify any actions taken that involve the exercise of the authorities delegated herein prior to the effective date of this delegation.

Dated: July 3, 2012.

**Thomas R. Frieden,**

*Director, CDC.*

[FR Doc. 2012-18466 Filed 7-30-12; 8:45 am]

**BILLING CODE 4160-18-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Community Living

#### Agency Information Collection Activities; Submission for OMB Review; Comment Request; Senior Medicare Patrol (SMP) Program Outcome Measurement

**AGENCY:** Administration for Community Living, HHS.

**ACTION:** Notice.

**SUMMARY:** The Administration for Community Living (ACL) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to Senior Medicare Patrol Program outcome measurement.

**DATES:** Submit written or electronic comments on the collection of information by October 1, 2012.

**ADDRESSES:** Submit electronic comments on the collection of information to:

*doris.summey@aoa.hhs.gov.*

Submit written comments on the collection of information to Administration for Community Living, Washington, DC 20201. Attention: Doris Summey.

**FOR FURTHER INFORMATION CONTACT:** Doris Summey, by telephone 202-357-3533 or by email: *doris.summey@aoa.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency request or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB

for approval. To comply with this requirement, ACL is publishing notice of the proposed collection of information set forth in this document. With respect to the following collection of information, ACL invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility; (2) the accuracy of ACL's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

Grantees are required by Congress to provide information for use in program monitoring and for Government Performance and Results Act (GPRA) purposes. This information collection reports the number of active volunteers, issues and inquiries received, other SMP program outreach activities, and the number of Medicare dollars recovered among other SMP performance outcomes.

ACL estimates the burden of this collection of information as follows: 54 SMP grantees at 23 hours per month (276 hours per year, per grantee). Total Estimated Burden Hours: 7,452 hours per year. The proposed data collection tool may be found on the AoA Web site for review at [http://www.aoa.gov/AoARoot/AoA\\_Programs/Tools\\_Resources/Cert\\_Forms.aspx](http://www.aoa.gov/AoARoot/AoA_Programs/Tools_Resources/Cert_Forms.aspx).

Dated: July 25, 2012.

**Kathy Greenlee,**

*Administrator and Assistant Secretary for Aging.*

[FR Doc. 2012-18645 Filed 7-30-12; 8:45 am]

**BILLING CODE 4154-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-D-0524]

#### Draft Guidance for Industry and Food and Drug Administration Staff; Acceptance and Filing Review for Premarket Approval Applications; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled “Acceptance and Filing Review for Premarket Approval Applications (PMAs).” The purpose of the acceptance and filing reviews is to make a threshold determination about whether an application is administratively complete. This guidance document is intended to clarify the criteria for accepting and filing a PMA, thereby assuring the consistency of our acceptance and filing decisions. This guidance is applicable to original PMAs and PMA panel-track supplements reviewed in the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research. This draft guidance is not final nor is it in effect at this time.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 14, 2012.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document entitled “Acceptance and Filing Review for Premarket Approval Applications (PMAs)” to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993-0002; or Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Nicole Wolanski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1650, Silver Spring,

MD 20993-0002, 301-796-6570; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

### I. Background

The PMA regulation (21 CFR 814.42(e)) identifies the criteria that, if not met, may serve as a basis for refusing to file a PMA. These criteria are discussed in the guidance document “Guidance for Industry and FDA Staff Premarket Approval Application Filing Review,” dated May 1, 2003. This document has been used by FDA staff and the device industry to help elucidate the broad preclinical and clinical issues that need to be addressed in a PMA and the key decisions to be made during the filing process.

To further focus the Agency’s review resources on complete applications, which will provide a more efficient approach to ensuring that devices that have a reasonable assurance of safety and effectiveness reach patients as quickly as possible, we have modified the PMA filing guidance. In this guidance entitled, “Acceptance and Filing Review for Premarket Approval Applications (PMAs),” we have separated the requirements for PMA filing into: (1) Acceptance criteria and (2) filing criteria. Acceptance review involves an early assessment of the completeness of the application, and informing the applicant in a written response within the first 15 calendar days of receipt of the application whether any administrative elements are missing, and if so, identifying the missing administrative element(s).

In order to enhance the consistency of our acceptance and filing decisions and to help applicants understand the types of information FDA needs to conduct a substantive review of a PMA, this guidance and associated checklist clarify the necessary elements and contents of a complete PMA application. The process we outline is applicable to all devices reviewed in a PMA application. Acceptance and filing decisions will be made for all original PMA applications and panel-track PMA supplements.

This guidance is not significantly different from the 2003 PMA guidance document. The “preliminary questions” remain the same and the “filing review questions” have been separated into “acceptance decision questions” (i.e., is the file administratively complete) and “filing decision questions” (i.e., are data consistent with the protocol, final device design, and proposed indications). In addition, it should be

noted that this document is focused on the regulatory and scientific criteria for making an “Accept” or “Refuse to Accept” decision as well as “File” or “Not File” decision for a PMA. It specifically does not alter the following administrative aspects of the PMA filing process: The timeframe for the filing review phase (i.e., 45 days); the processes for document tracking, distribution, and handling; and the procedures for assembling the review team and setting up the filing meeting.

### II. 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 acceptance and filing reviews for PMAs. 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.

### III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. To receive “Acceptance and Filing Review for Premarket Approval Applications (PMAs),” you may either send an email request to [smica@fda.hhs.gov](mailto:smica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1792 to identify the guidance you are requesting.

### IV. Paperwork Reduction Act of 1995

This draft guidance refers to currently approved collections of information found in FDA regulations. These collections of information 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 collections of information in 21 CFR part 814, subpart B, have been approved under OMB control number 0910-0231.

### V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments 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: July 24, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2012-18603 Filed 7-30-12; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0785]

#### Medical Device User Fee Rates for Fiscal Year 2013

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the fee rates and payment procedures for medical device user fees for fiscal year (FY) 2013. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device User Fee Amendments of 2012 (Title 2 of the Food and Drug Administration Safety and Innovation Act, Public Law 112-144, which was signed by the President on July 9, 2012) (MDUFA III), authorizes FDA to collect user fees for certain medical device submissions, and annual fees both for certain periodic reports and for establishments subject to registration. The FY 2013 fee rates are provided in this document. These fees apply from October 1, 2012, through September 30, 2013. To avoid delay in the review of your application, you should pay the fee before or at the time you submit your application to FDA. The fee you must pay is the fee that is in effect on the later of the date that your application is received by FDA or the date your fee payment is recognized by the U.S. Treasury. If you want to pay a reduced small business fee, you must qualify as a small business before you make your submission to FDA; if you do not qualify as a small business before you make your submission to FDA, you will have to pay the higher standard fee. This document provides information on how the fees for FY 2013 were determined, the payment procedures

you should follow, and how you may qualify for reduced small business fees.

**FOR FURTHER INFORMATION CONTACT:** *For information on Medical Device User Fees:* Visit FDA's Web site, <http://www.fda.gov/mdufa>.

*For questions relating to this notice:* David Miller, Office of Financial Management (HFA-100), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-796-7103.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Section 738 of the FD&C Act (21 U.S.C 379j) establishes fees for certain medical device applications, submissions, supplements, and notices (for simplicity, this document refers to these collectively as "submissions" or "applications"); for periodic reporting on class III devices; and for the registration of certain establishments. Under statutorily-defined conditions, a qualified applicant may receive a fee waiver or may pay a lower small business fee. (See 21 U.S.C. 379j(d) and (e).) Additionally, the Secretary may, at the Secretary's sole discretion, grant a fee waiver or reduction if the Secretary finds that such waiver or reduction is in the interest of public health. (See 21 U.S.C. 379j(f).)

Under the FD&C Act, the fee rate for each type of submission is set at a specified percentage of the standard fee for a premarket application (a premarket application is a premarket approval application (PMA), a product development protocol (PDP), or a biologics license application (BLA)). The FD&C Act specifies the base fee for a premarket application for each year from FY 2013 through FY 2017; the base fee for a premarket application received by FDA during FY 2013 is \$248,000. From this starting point, this document establishes FY 2013 fee rates for other types of submissions, and for periodic reporting, by applying criteria specified in the FD&C Act.

The FD&C Act specifies the base fee for establishment registration for each year from FY 2013 through FY 2017; the registration fee for FY 2013 is \$2,575. There is no reduction in the registration fee for small businesses. Each establishment that is registered (or is required to register) with the Secretary under section 510 of the FD&C Act (21 U.S.C. 360) because such establishment is engaged in the manufacture,

preparation, propagation, compounding, or processing of a device is required to pay the annual fee for establishment registration.

##### II. Fees for FY 2013

Under the FD&C Act, all submission fees and the periodic reporting fee are set as a percent of the standard (full) fee for a premarket application. (See 21 U.S.C. 379j(a)(2)(A).) For FY 2013, the standard fee is the base fee; for FY 2014 through FY 2017, the base fee will be adjusted as specified in the FD&C Act so for these fiscal years, the standard fee will be the adjusted base fee. (See 21 U.S.C. 379j(b) and (c).) The standard fee for a premarket application, including a BLA, and for a premarket report and a BLA efficacy supplement, is \$248,000 for FY 2013. (See 21 U.S.C. 379j(b).) The fees set by reference to the standard fee for a premarket application are:

- For a panel-track supplement, 75 percent of the standard fee;
- For a 180-day supplement, 15 percent of the standard fee;
- For a real-time supplement, 7 percent of the standard fee;
- For a 30-day notice, 1.6 percent of the standard fee;
- For a 510(k) premarket notification, 2 percent of the standard fee;
- For a 513(g) request for classification information, 1.35 percent of the standard fee; and
- For an annual fee for periodic reporting concerning a class III device, 3.5 percent of the standard fee.

For all submissions other than a 510(k) premarket notification, a 30-day notice, and a 513(g) request for classification information, the small business fee is 25 percent of the standard (full) fee for the submission. (See 21 U.S.C. 379j(d)(2)(C).) For a 510(k) premarket notification submission, a 30-day notice, and a 513(g) request for classification information, the small business fee is 50 percent of the standard (full) fee for the submission. (See 21 U.S.C. 379j(d)(2)(C) and (e)(2)(C).)

The statute sets the annual fee for establishment registration at \$2,575 in FY 2013. There is no small business rate for the annual establishment registration fee; all establishments pay the same fee.

Table 1 of this document set out the FY2013 rates for all medical device fees.