

**FOR FURTHER INFORMATION CONTACT:**

Evella Washington, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G640, Silver Spring, MD 20993-0002, *Evella.Washington@fda.hhs.gov*, 301-796-6683, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572) in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

**SUPPLEMENTARY INFORMATION:**

**Agenda:** On June 19 and 20, 2019, the committee will discuss and make recommendations on information related to recent observations of increased long-term mortality in peripheral arterial disease patients treated with paclitaxel-coated balloons and paclitaxel-eluting stents compared to patients treated with uncoated comparator devices. FDA requests panel input regarding the presence and magnitude of the signal and potential causes. FDA also seeks input regarding appropriate regulatory actions associated with the findings.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

**Procedure:** Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person (see **FOR FURTHER INFORMATION**

**CONTACT**) on or before May 22, 2019. Oral presentations from the public will be scheduled on June 19, 2019, between approximately 1 p.m. and 2 p.m.; and on June 20, 2019, between approximately 10:30 a.m. and 11:30 a.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 14, 2019. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 15, 2019.

Representatives from industry, professional organizations, and societies interested in making formal presentations to the committee should notify the contact person on or before May 22, 2019.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Artair Mallett at *Artair.Mallett@fda.hhs.gov* or 301-796-9638 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 2).

Dated: April 17, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019-08033 Filed 4-19-19; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

[Document Identifier: 4040-0004]

**Agency Information Collection Request. 60-Day Public Comment Request**

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

**DATES:** Comments on the ICR must be received on or before June 21, 2019.

**ADDRESSES:** Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 795-7714.

**FOR FURTHER INFORMATION CONTACT:**

When submitting comments or requesting information, please include the document identifier 4040-0004-60D and project title for reference to *Grants.gov* Manager, Ed Calimag, at *ed.calimag@hhs.gov* or 202-690-7569.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Title of the Collection:* Application for Federal Assistance (SF-424).

*Type of Collection:* Reinstatement without change.

OMB No. 4040-0004.

*Abstract:* The Application for Federal Assistance (SF-424) form provides the Federal grant-making agencies with a common and standard form for organizations to apply for financial assistance.

*Type of respondent:* Organizations seeking financial assistance. This form is submitted to the Federal grant-making agencies for evaluation and review.

## ANNUALIZED BURDEN HOUR TABLE

Form	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Application for Federal Assistance (SF-424) .....	Grant applicants .....	20,803	1	1	20,803
Total .....	.....	20,803	1	1	20,803

**Terry Clark,**

*Assistant Information Collection Clearance Officer.*

[FR Doc. 2019-07958 Filed 4-19-19; 8:45 am]

**BILLING CODE 4151-AE-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

[Document Identifier: 4040-0005]

**Agency Information Collection Request; 60-Day Public Comment Request**

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

**DATES:** Comments on the ICR must be received on or before June 21, 2019.

**ADDRESSES:** Submit your comments to [Sherrette.Funn@hhs.gov](mailto:Sherrette.Funn@hhs.gov) or by calling (202) 795-7714.

**FOR FURTHER INFORMATION CONTACT:**

When submitting comments or requesting information, please include the document identifier 4040-0005-60D and project title for reference to *Grants.gov* Manager, Ed Calimag, at [ed.calimag@hhs.gov](mailto:ed.calimag@hhs.gov) or 202-690-7569.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection

techniques or other forms of information technology to minimize the information collection burden.

*Title of the Collection:* Application for Federal Assistance—Individual.

*Type of Collection:* Reinstatement without change.

OMB No. 4040-0005.

*Abstract:* The Application for Federal Assistance—Individual form provides the Federal grant-making agencies an alternative to the Standard Form 424 data set and form. Agencies may use Application for Federal Assistance—Individual form for grant programs not required to collect all the data that is required on the SF-424 core data set and form.

*Type of respondent:* The Application for Federal Assistance—Individual form is used by organizations to apply for Federal financial assistance in the form of grants. This form is submitted to the Federal grant-making agencies for evaluation and review.

## ANNUALIZED BURDEN HOUR TABLE

Forms	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Application for Federal Assistance—Individual .....	Grant applicants .....	0	1	1	0
Total .....	.....	0	1	1	0

**Terry Clark,**

*Assistant Information Collection Clearance Officer.*

[FR Doc. 2019-07959 Filed 4-19-19; 8:45 am]

**BILLING CODE 4151-AE-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

[Document Identifier: 4040-0001]

**Agency Information Collection Request; 60-Day Public Comment Request**

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork

Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

**DATES:** Comments on the ICR must be received on or before June 21, 2019.

**ADDRESSES:** Submit your comments to [Sherrette.Funn@hhs.gov](mailto:Sherrette.Funn@hhs.gov) or by calling (202) 795-7714.

**FOR FURTHER INFORMATION CONTACT:**

When submitting comments or requesting information, please include the document identifier 4040-0001-60D and project title for reference to *Grants.gov* Manager, Ed Calimag, at [ed.calimag@hhs.gov](mailto:ed.calimag@hhs.gov) or 202-690-7569.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to send comments

regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Title of the Collection:* Application for Federal Assistance SF 424 R&R forms.

*Type of Collection:* Reinstatement without change.

OMB No.: 4040-0001.