

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
CDRH Appeals Processes Guidance Document	50	1	50	8	400

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

Dated: October 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–26672 Filed 10–20–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0427]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Inspection by Accredited Persons Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002.

DATES: Submit either electronic or written comments on the collection of information by December 21, 2015.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any

confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions”.

Instructions: All submissions received must include the Docket No. FDA–2012–N–0427 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Inspection by Accredited Persons Program”. Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS

CONFIDENTIAL INFORMATION”. The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, PRASStaff@fda.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 requests 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, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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.

Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002—OMB Control Number 0910-0510—Extension

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA)

(Pub. L. 107-250) was signed into law on October 26, 2002. Section 201 of MDUFMA added a new paragraph (g) to section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374), directing FDA to accredit third parties (accredited persons) to conduct inspections of eligible manufacturers of class II or class III devices. FDA's guidance document entitled "Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria" provides information for those interested in participating in this voluntary program.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Request for accreditation	1	1	1	80	80

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

Dated: October 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-26641 Filed 10-20-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting Notice for the President's Advisory Council on Faith-based and Neighborhood Partnerships

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the President's Advisory Council on Faith-based and Neighborhood Partnerships announces the following meetings:

Name: President's Advisory Council on Faith-based and Neighborhood Partnerships Council Meetings

Time and Date: Thursday, November 5th, 2015 1:00 p.m.–4:30 p.m. (EST) and Friday, November 6th, 2015 9:30 a.m.–12:30 p.m. (EST)

Place: Meeting will be held at a location to be determined in the White House complex, 1600 Pennsylvania Ave. NW., Washington, DC. Space is extremely limited. Photo ID and RSVP are required to attend the event. Please RSVP to Ben O'Dell at partnerships@hhs.gov

The meeting will be available to the public through a conference call line. Register to participate in the conference call on Thursday, November 5th at the Web site <https://>

attendee.gotowebinar.com/register/7500158409923624193. Register to participate in the conference call on Friday, November 6th at the Web site <https://attendee.gotowebinar.com/register/8566024981889767937>.

Status: Open to the public, limited only by space available. Conference call limited only by lines available.

Purpose: The Council brings together leaders and experts in fields related to the work of faith-based and neighborhood organizations in order to: Identify best practices and successful modes of delivering social services; evaluate the need for improvements in the implementation and coordination of public policies relating to faith-based and other neighborhood organizations; and make recommendations for changes in policies, programs, and practices.

Contact Person for Additional Information: Please contact Ben O'Dell for any additional information about the President's Advisory Council meeting at partnerships@hhs.gov

Agenda: More information for the agenda for the meeting will be provided to those who register to attend in person or by conference call.

Public Comment: There will be an opportunity for public comment at the end of the meeting. Comments and questions can be sent in advance to partnerships@hhs.gov.

Dated: October 9, 2015.

Ben O'Dell,

Associate Director.

[FR Doc. 2015-26407 Filed 10-20-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Collaborative Research in Integrative Cancer Biology (U01).

Date: November 19, 2015.

Time: 11:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.