

Attn: Desk Officer for the  
Administration for Children and  
Families.

**Robert Sargis,**  
*ACF Reports Clearance Officer.*  
[FR Doc. 2013–19929 Filed 8–15–13; 8:45 am]  
**BILLING CODE 4184–09–P**

**DEPARTMENT OF HEALTH AND  
HUMAN SERVICES**

**Food and Drug Administration**  
[Docket No. FDA–2009–N–0380]

**Agency Information Collection  
Activities; Submission for Office of  
Management and Budget Review;  
Comment Request; Product  
Jurisdiction: Assignment of Agency  
Component for Review of Premarket  
Applications**

**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 September  
16, 2013.

**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:  
202–395–7285, or emailed to  
*oira\_submission@omb.eop.gov*. All  
comments should be identified with the  
OMB control number 0910–0523. Also  
include the FDA docket number found  
in brackets in the heading of this  
document.

**FOR FURTHER INFORMATION CONTACT:**  
Jonna Capezzuto, Office of Operations,  
Food and Drug Administration, 1350  
Piccard Dr., PI50–400B, Rockville, MD  
20850, 301–796–3794,  
*Jonnalynn.capezzuto@fda.hhs.gov*.

**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.

**Product Jurisdiction: Assignment of  
Agency Component for Review of  
Premarket Applications—(OMB Control  
Number 0910–0523)—Extension**

This regulation relates to Agency  
management and organization and has  
two purposes. The first is to implement  
section 503(g) of the Federal Food, Drug,  
and Cosmetic Act (21 U.S.C. 353(g)), as  
added by the Safe Medical Devices Act  
of 1990 (Pub. L. 101–629), and amended  
by the Medical Device User Fee and  
Modernization Act of 2002 (Pub. L. 107–  
250), by specifying how FDA will  
determine the organizational component  
within FDA assigned to have primary  
jurisdiction for the premarket review  
and regulation of products that are  
comprised of any combination of: (1) A  
drug and a device; (2) a device and a

biological product; (3) a biological  
product and a drug; or (4) a drug, a  
device, and a biological product. The  
second purpose of this regulation is to  
enhance the efficiency of Agency  
management and operations by  
providing procedures for classifying and  
determining which Agency component  
is designated to have primary  
jurisdiction for any drug, device, or  
biological product where such  
jurisdiction is unclear or in dispute.

The regulation establishes a  
procedure by which an applicant may  
obtain an assignment or designation  
determination. The regulation requires  
that the request include the identity of  
the applicant, a comprehensive  
description of the product and its  
proposed use, and the applicant's  
recommendation as to which Agency  
component should have primary  
jurisdiction, with an accompanying  
statement of reasons. The information  
submitted would be used by FDA as the  
basis for making the assignment or  
designation decision. Most information  
required by the regulation is already  
required for premarket applications  
affecting drugs, devices, biological  
products, and combination products.  
The respondents will be businesses or  
other for-profit organizations.

In the **Federal Register** of May 2, 2013  
(78 FR 25746), FDA published a 60-day  
notice requesting public comment on  
the proposed collection of information.  
No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR Part	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Part 3 .....	59	1	59	24	1,416

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

These burden estimates are based on  
the number of applications FDA  
received over the past 2 fiscal years.

Dated: August 12, 2013.

**Leslie Kux,**  
*Assistant Commissioner for Policy.*  
[FR Doc. 2013–19916 Filed 8–15–13; 8:45 am]  
**BILLING CODE 4160–01–P**

**DEPARTMENT OF HEALTH AND  
HUMAN SERVICES**

**National Institutes of Health**

**National Cancer Institute; Notice of  
Meeting**

Pursuant to section 10(a) of the  
Federal Advisory Committee Act, as  
amended (5 U.S.C. App.), notice is  
hereby given of a meeting of the  
President's Cancer Panel.

The meeting will be open to the  
public, with attendance limited to space  
available. Individuals who plan to  
attend and need special assistance, such

as sign language interpretation or other  
reasonable accommodations, should  
notify the Contact Person listed below  
in advance of the meeting.

*Name of Committee:* President's Cancer  
Panel.

*Date:* October 11, 2013.

*Time:* 8:30 a.m. to 3:30 p.m.

*Agenda:* Cancer Communication for  
Prevention: In the Digital Commons,  
Opportunities Amongst the Challenges.

*Place:* National Institutes of Health, 9000  
Rockville Pike, Building 31, C–Wing, 6th  
Floor, Conference Room 10, Bethesda, MD  
20892.

*Contact Person:* Abby B. Sandler, Ph.D.,  
Executive Secretary, President's Cancer  
Panel, Special Assistant to the Director, NCI