

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[30 Day–12–0556]

**Agency Forms Undergoing Paperwork Reduction Act Review**

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–7570 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov). Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

**Proposed Project**

Assisted Reproductive Technology (ART) Program Reporting System (0920–0556, exp. 9/30/2012)—Revision—National Center for Chronic Disease and Public Health Promotion (NCDDPHP),

Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

The ART program reporting system is used to comply with Section 2(a) of Public Law 102–493 (known as the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA)), 42 U.S.C. 263a–1(a)). FCSRCA requires each ART program to annually report to the Secretary through the CDC pregnancy success rates achieved by each ART program, the identity of each embryo laboratory used by such ART program, and whether the laboratory is certified or has applied for certification under the Act. The reporting system allows CDC to publish an annual success rate report to Congress as specified by the FCSRCA.

CDC requests OMB approval to continue information collection for three years. This Revision request includes an increase in the total estimated burden hours due to an increase in the estimated number of responding clinics and an increase in the estimated number of responses per respondent. In addition, this Revision request describes implementation of a brief, one-time optional feedback survey at the end of the data submission for

each reporting year. The feedback survey will elicit information about ART reporting system usability as well as respondents’ perspectives on the usefulness of the information collection.

Information is collected electronically through the National ART Surveillance System (NASS), a web-based interface, or by electronic submission of NASS-compatible files. The NASS includes information about all ART cycles initiated by any of the ART programs practicing in the United States and its territories. The system also collects information about the pregnancy outcome of each cycle as well as a number of data items deemed important to explain variability in success rates across ART programs and individuals.

Respondents are the 484 ART programs in the United States. Approximately 440 ART programs are expected to report an average of 339 ART cycles each. The burden estimate includes the time for collecting, validating, and reporting the requested information. Information is collected on an annual schedule.

There are no costs to the respondents other than their time. The total estimated annualized burden hours are 96,960.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
ART Programs .....	NASS .....	440	339	39/60
	Feedback Survey .....	176	1	2/60

**Kimberly S. Lane,**

*Deputy Director, Office of Science Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.*

[FR Doc. 2012–17292 Filed 7–13–12; 8:45 am]

**BILLING CODE 4163–18–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2012–N–0001]

**Advisory Committee for Pharmaceutical Science and Clinical Pharmacology; Notice of Meeting**

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee

of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Advisory Committee for Pharmaceutical Science and Clinical Pharmacology.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA’s regulatory issues.

*Date and Time:* The meeting will be held on August 9, 2012, from 8 a.m. to 5 p.m.

*Location:* FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading “Resources for You,” click on “Public Meetings at the FDA White Oak Campus.” Please note that visitors

to the White Oak Campus must enter through Building 1.

*Contact Person:* Yvette Waples, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: [ACPS-CP@fda.hhs.gov](mailto:ACPS-CP@fda.hhs.gov), or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), to find out further information regarding FDA advisory committee information. 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 Web site at <http://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.

*Agenda:* During the morning session, the committee will discuss FDA's draft guidance on tablet scoring. This topic will include an overview of FDA's proposed plan to move forward and the United States Pharmacopoeia's perspective on the topic. During the afternoon session, the committee will discuss: (1) The Center for Drug Evaluation and Research (CDER) Nanotechnology Risk Management Working Group activities; (2) nanotechnology-related research conducted and published by CDER, to include examples related to sunscreens; and (3) the overview and preliminary analysis of nanotechnology-related information collected from drug application submissions.

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 Web site 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 Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee 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 on or before July 26, 2012. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11 a.m. for the morning session, and 3:15 p.m. to 3:45 p.m. for the afternoon session. 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 July 18, 2012. 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 July 19, 2012.

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 physical disabilities or special needs. If you require special accommodations due to a disability, please contact Yvette Waples at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://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. app. 2).

Dated: July 10, 2012.

**Jill Hartzler Warner,**  
*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2012-17193 Filed 7-13-12; 8:45 am]

**BILLING CODE 4160-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Proposed Collection; Comment Request; Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO) (NCI)**

**SUMMARY:** In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

*Proposed Collection: Title:* Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial (PLCO) (NCI). *Type of Information Collection Request:* Revision (OMB #: 0925-0407, current expiration date 9/30/2014). *Need and Use of Information Collection:* This trial was designed to determine if cancer screening for prostate, lung, colorectal, and ovarian cancer can reduce mortality from these cancers which currently cause an estimated 255,700 deaths annually in the U.S. The design is a two-armed randomized trial of men and women aged 55 to 74 at entry. OMB first approved this study in 1993 and has approved it every 3 years since. The main change to this submission is that the Supplemental Questionnaire is being replaced with the Medication Use Questionnaire. As PLCO participants now range from 74-94 years of age, the focus is now on collecting additional information regarding medications that are particularly common among older adults. Additionally, the contracts for 8 of the 10 Screening Centers (SCs) ended in 2011 and the remaining two sites will close in 2012 and 2014. NCI has awarded a contract for continuation of participant follow-up activities to one data collection site named the PLCO Central Data Collection Center (CDCC). In 2011, participants were re-consented for at least an additional five years of follow-up. The current number of respondents is limited to the approximately 94,000 participants being actively followed up. The reports on cancer screening and prostate, lung, colorectal, and ovarian cancer mortality based on this trial have been published in peer review medical journals. The additional follow-up will provide data that will clarify further the long term effects of the screening on cancer incidence and mortality for the four targeted cancers. Further, demographic and risk factor information may be used to analyze the differential effectiveness of cancer screening in high versus low risk individuals. *Frequency of Response:* Annually. *Affected Public:* Individuals. *Type of Respondents:* Adult men and women. The annual reporting burden is provided for each study component as shown in Table 1 below. There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

TABLE 1—ESTIMATES OF ANNUAL BURDEN HOURS

Type of respondents	Survey instrument	Number of respondents	Frequency of response	Average time per response (minutes/hour)	Annual burden hours
Male and female participants.	ASU .....	94,000 .....	1.00	5/60	7,833