EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN—Continued

Activity name	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Key Informant Interviews with EHC Stakeholder Group Members	2	2	43.52	87
Key Informant Interviews with EHC Program Users and Stakeholders	19	19	46.73	888
Online Survey with EHC Program Users and Stakeholders	170	43	46.73	2,009
Key Informant Interviews with EHC Program Users and Stakeholders to Develop Cases	25	25	46.73	1,168
Appreciative Inquiry Workshop	20	120	51.14	6,137
Total	344	246	na	12,297

*Wage rates were calculated using the following data: (1) For the Governance Interviews and the Online Survey with EHC Research Centers Staff the hourly rate is a weighted average for physicians ($58.76 per hour) and medical and health services managers ($37.82); (2) for the Governance Interviews with EHC Stakeholder Group Members the hourly rate is the rate for average for medical and health services managers ($37.82); (3) for the Governance Interviews and the Online Survey with EHC Program Users and Stakeholders the hourly rate is a weighted average for physicians ($58.76 per hour), general and operations managers ($43.52 per hour), medical and health services managers ($37.82 per hour), and social and community service managers ($24.73 per hour); (4) for the Workshop the hourly rate is a weighted average for physicians ($58.76 per hour) and general and operations managers ($43.52 per hour) from the mean of the average wages, National Compensation Survey: Occupational Wages in the United States 2006, U.S. Department of Labor, Bureau of Labor Statistics.

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the estimated cost of this one year data collection for the evaluation of the EHC program, including the cost of developing the methodology and data collection instruments, collecting and analyzing the data, publishing the results, etc. The work will be carried out by IMPAQ International and Abt Associates under contract to the Agency for Healthcare Research and Quality.

EXHIBIT 3—ESTIMATED ANNUAL COST TO THE FEDERAL GOVERNMENT

Cost component	Total cost
Project Development	$137,901
Data Collection Activities	179,172
Data Processing and Analysis	170,577
Publication of Results	63,686
Project Management	97,236
Total	648,572

*Please note the costs include fully loaded costs (overhead, G&A).

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: July 2, 2009.

Carolyn M. Clancy,

Director.

[FR Doc. E9–16568 Filed 7–13–09; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0212]

Draft Guidance for Industry on ''Incorporation of Physical-Chemical Identifiers into Solid Oral Dosage Form Drug Products for Anticounterfeiting,'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Incorporation of Physical-Chemical Identifiers into Solid Oral Dosage Form Drug Products for Anticounterfeiting.'' This draft guidance provides recommendations to pharmaceutical manufacturers on design considerations for incorporating physical-chemical identifiers (PCIDs) into solid oral dosage forms (SODFs), supporting documentation to be submitted in new drug applications (NDAs) and abbreviated new drug applications (ANDAs) to address the proposed incorporation of PCIDs in SODFs, supporting documentation to be submitted in postapproval submissions to report or request approval to incorporate PCIDs into SODFs, and procedures for reporting or requesting approval to incorporate PCIDs into SODFs as a postapproval change. This draft guidance also provides our recommendations regarding evaluation of toxicological and other concerns for PCIDs that are incorporated into packaging and labeling and procedures for reporting or requesting approval to add PCIDs to packaging and containers as a postapproval change.

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 written or electronic comments on the draft guidance by October 13, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: John L. Smith, Center for Drug Evaluation and Research, Food and Drug Administration, 10993 New Hampshire Ave., Building 21, rm. 2619, Rockville, MD 20857, 301–796–1757.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Incorporation of Physical-Chemical Identifiers into Solid Oral Dosage Form Drug Products for Anticounterfeiting.'' Pharmaceutical manufacturers aiming to thwart drug product counterfeiting have been investigating readily available technologies to make drug products more difficult to duplicate. One approach that pharmaceutical manufacturers appear to be considering involves adding a trace amount of an inactive ingredient(s) to an existing section of the dosage form. A unique physical-chemical characteristic of that ingredient makes it possible to detect and authenticate legitimate dosage forms and identify counterfeits.

This draft guidance provides recommendations to pharmaceutical manufacturers on the following topics: (1) Design considerations for incorporating PCIDS into SODFs, (2) supporting documentation to be submitted with NDAs and ANDAs to address the proposed incorporation of PCIDs in SODFs, (3) supporting documentation to be submitted in postapproval submissions to report or request approval to incorporate PCIDs into SODFs, and (4) procedures for reporting or requesting approval to incorporate PCIDs into SODFs as a postapproval change. This draft guidance also provides our recommendations regarding: (1) Evaluation of toxicological and other concerns for PCIDs that are incorporated into packaging and labeling and (2) procedures for reporting or requesting approval to add PCIDs to packaging and containers as a postapproval change.

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 ''Incorporation of Physical-Chemical Identifiers into Solid Oral Dosage Form Drug Products for Anticounterfeiting.'' 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 statutes and regulations.

II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that 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 documentation in premarketing regulatory submissions recommended for applicants incorporating PCIDs into SODFs would be covered under 21 CFR 314.50 and 314.94, and the documentation in postapproval regulatory submissions would be covered under 21 CFR 314.70. This information collection is approved by OMB under OMB control number 0910–0001.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.regulations.gov*.

Dated: July 6, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–16612 Filed 7–13–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0313]

Dual Antiplatelet Therapy Trial: Research Project Grant (R01)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of the Office of Critical Path Programs (OCPP). The goal of the Dual Antiplatelet Therapy (DAPT) Trial is to solicit a sole source grant application from Harvard Clinical Research Institute (HCRI) that proposes to provide funding in support of a dual antiplatelet therapy clinical trial being conducted by HCRI.

DATES: Important dates are as follows:

1. The application due date is August 12, 2009.
2. The anticipated start date is in September 2009.
3. The opening date is July 14, 2009.
4. The expiration date is in May 2010.

FOR FURTHER INFORMATION AND ADDITIONAL REQUIREMENTS CONTACT:

Nancy Stanisic, Office of Critical Path Programs (HF–18), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1660.

Vieda Hubbard, Office of Acquisitions and Grants Services, (HFA–500), Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20857, 301–827–7177.

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at *http://www.fda.gov/oc/initiatives/criticalpath/*.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

Request for Applications (RFA) Number: RFA–FD–09–016
Catalog of Federal Domestic Assistance Number: 93.103

A. Background

OCPP is soliciting a sole source grant application from HCRI that proposes to provide funding in support of a dual antiplatelet therapy clinical trial being conducted by HCRI.

Given the lack of randomized data, there is considerable uncertainty in the medical community about the optimal duration of dual antiplatelet therapy following Percutaneous Cardiac Intervention. It is unclear as to whether the duration of dual antiplatelet therapy in patients receiving Drug Eluting Stents (DES) should be 3 to 6 months (as was prescribed in the pivotal DES randomized trials conducted for premarket approval), 12 months (as per the American College of Cardiology/American Heart Association/Society for Cardiac Angiography and Interventions guidelines), or even longer. It is also unknown whether the presumed benefit of extended dual antiplatelet therapy is specific to DES or whether non-Acute Coronary Syndrome patients treated with BMS (e.g. stable angina) may also benefit from extended dual antiplatelet therapy. With these considerations in