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FDA is announcing the availability of a draft guidance for industry entitled ''Incorporation of Physical-Chemical Identifiers into Solid Oral Dosage Form Drug Products for Anticounterfeiting.''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This draft guidance provides recommendations to pharmaceutical manufacturers on the following topics: (1) Design considerations for incorporating PCIDS into SODFs, (2) supporting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 This draft guidance also provides our recommendations regarding: (1) Evaluation of toxicological and other concerns for PCIDs that are incorporated into packaging and labeling and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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on ''Incorporation of Physical-Chemical Identifiers into Solid Oral Dosage Form Drug Products for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This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction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

mind, it is imperative that the risks and benefits of continued clopidogrel use be evaluated to determine, with greater precision, the optimal duration of dual anti-platelet therapy. This trial will be conducted with the unprecedented cooperation of four device manufacturers and two drug manufacturers under the direction of HCRI.

B. Research Objectives

The Research Project Grant (R01) is an award to support a discrete, specified, circumscribed project to be performed by HCRI in areas representing the investigators' specific interests and competencies based on the mission of FDA. The development of the DAPT trial represents an important and critical new paradigm for FDA and the medical product development community —having identified a critical public health issue in a combination product that impacts hundreds of thousands of American patients, the device and drug industries are collaborating together to address this question with a single trial. The advantages of this concerted effort are obvious—obtaining an answer more quickly and with fewer resources expended. The study is unprecedented in the level of cooperation, both internal and external, that is required.

FDA awards R01 grants to institutions/organizations of all types. This mechanism allows the program directors/principal investigators (PDs/PIs) to define the scientific focus or objective of the research based on particular areas of interest and competence. Although the PDs/PIs write the grant application and are responsible for conducting and supervising the research, the actual applicant is the research institution/organization.

One of OCPP's mandates is to identify and promote the development of collaborative partnerships and support mechanisms of innovative trial design. Innovative clinical trial design may make it possible to develop accepted protocols for smaller but smarter trials or trials that can be conducted with collaboration of multiple device and drug manufacturers. The development of the DAPT trial represents an important and critical new paradigm for FDA. When a critical public health issue is identified in a combination product that impacts thousands of American patients, the concerted effort of multiple parts of the agency can bring the members of the regulated industry and clinical community to develop a clinical trial that will provide the answers needed by practicing physicians.

C. Eligibility Information

This award will be made to HCRI.

II. Award Information/Funds Available

A. Award Amount

The total amount of funding that the agency expects to award through this announcement is $1.5 million. There will be one award.

B. Length of Support

The total project period for the application submitted in response to this funding opportunity may not exceed 2 years.

III. How to Submit a Paper Application

To submit a paper application in response to this FOA, applicants should first review the full announcement located at *http://www.fda.gov/oc/initiatives/criticalpath/*. Persons interested in applying for a grant may obtain an application form at *http://grants.nih.gov/grants/forms.htm*. For all paper submissions, the following steps are required:

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number
- Step 2: Register With Central Contractor Registration
- Step 3: Register With Electronic Research Administration (eRA) Commons

Steps 1 and 2, in detail, can be found at *http://www07.grants.gov/applicants/organization_registration.jsp*. Step 3, in detail, can be found at *https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp*. After you have followed these steps, submit paper applications to: Vieda Hubbard (see **FOR FURTHER INFORMATION AND ADDITIONAL REQUIREMENTS CONTACT**).

Dated: July 8, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–16695 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–2007–D–0434 (Formerly Docket No. 2007D–0386)]

Guidance for Industry on Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application.'' This document provides guidance to industry on postmarketing serious adverse event reporting for nonprescription (over-the-counter (OTC)) human drugs marketed without an approved application. It gives guidance on the minimum data elements that should be included in a serious adverse event report, the label that should be included with the report, reporting formats for paper and electronic submissions, and how and where to submit the reports. Separate guidance, issued by FDA's Center for Food Safety and Applied Nutrition on adverse event reporting for dietary supplements, is announced elsewhere in this issue of the **Federal Register**.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this 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 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Kathleen Frost, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4312, Silver Spring, MD 20993–0002, 301–796–2380.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application.'' Public Law 109–462, the Dietary Supplement and Nonprescription Drug Consumer Protection Act, enacted on December 22, 2006, required FDA to issue guidance on the minimum data elements that should be included in a serious adverse