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

event report (section 2(e)(3)). The guidance document provides information on the following topics: (1) The minimum data elements that should be included in a serious adverse event report, (2) the label that should be included with the report, (3) reporting formats for paper and electronic submissions, and (4) how and where to submit the reports.

Public Law 109–462 amends the Federal Food, Drug, and Cosmetic Act (the act) to add safety reporting requirements for nonprescription drug products that are marketed without an approved application. In accordance with section 760(b) of the act (21 U.S.C. 379aa), the manufacturer, packer, or distributor whose name appears on the label of a nonprescription drug marketed in the United States without an approved application (referred to as the ''responsible person'') must submit to FDA any report of a serious adverse event associated with such drug when used in the United States, accompanied by a copy of the label on or within the retail package of such drug. In addition, the responsible person must submit followup reports of new medical information related to a submitted serious adverse event report that is received within 1 year of the initial report (section 760(c)(2) of the act). Public Law 109–462 also requires certain postmarketing safety report!s for dietary supplements.

In the **Federal Register** of October 15, 2007 (72 FR 58316), FDA announced the availability of a draft guidance of the same title. FDA received several comments on the draft guidance and considered those comments when finalizing the guidance. The guidance announced in this notice finalizes the draft guidance dated October 2007.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on postmarketing adverse event reporting for nonprescription human drug products marketed without an approved application. 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. Paperwork Reduction Act of 1995

This guidance contains information collection provisions 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 collections of information in this guidance have been approved under OMB Control No. 0910–0636.

### 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: July 8, 2009.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

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**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2007–D–0372] (Formerly Docket No. 2007D–0388)**

## Guidance for Industry: Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act.'' The document provides guidance to the dietary supplement industry for complying with the serious adverse event reporting and recordkeeping requirements prescribed for dietary supplement manufacturers, packers, and distributors by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (the DSNDCPA). Separate guidance, issued by FDA's Center for Drug Evaluation and Research, on reporting for nonprescription (over-the-counter (OTC)) human drugs marketed without an approved application, is announced elsewhere in this issue of the **Federal Register**.

**DATES:** Submit written or electronic comments on the guidance at any time.

**ADDRESSES:** 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 on the guidance to *http://www.regulations.gov*. Submit written requests for single copies of the guidance to the Office of Nutrition, Labeling, and Dietary Supplements (HFS–800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20750. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

**FOR FURTHER INFORMATION CONTACT:** Vasilios Frankos,Center for Food Safety and Applied Nutrition (HFS–810), Food and Drug Administration,5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2375.

**SUPPLEMENTARY INFORMATION:**

### I. Background

In the **Federal Register** of October 15, 2007 (72 FR 58313), FDA announced the availability of a draft guidance entitled ''Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act'' and gave interested parties an opportunity to submit comments by December 14, 2007. The agency reviewed and evaluated these comments and has modified the guidance where appropriate.

The guidance contains questions and answers relating to the new requirements under the DSNDCPA, concerning the mandatory reporting to FDA of serious adverse events associated with dietary supplements, the minimum data elements to be submitted in such reports, and records of serious and non-serious adverse events reported to a dietary supplement manufacturer, packer, or distributor.

FDA is issuing this guidance as level 1 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the