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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

2008-D-0180

[Docket No. FDA-

Draft Guidance for Industry on Developing Coronary Drug Eluting Stents; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of a public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled "Coronary Drug-Eluting Stent (DES) Guidance Document Workshop." FDA is cosponsoring the workshop with the Advanced Medical Technology Association (AdvaMed). The purpose of the workshop is to discuss the draft guidance entitled "Coronary Drug-Eluting Stents: Nonclinical and Clinical Studies" announced in the **Federal Register** of March 27, 2008, and its companion document entitled "Coronary Drug-Eluting Stents-Nonclinical and Clinical Studies (Companion Document)" (the Companion Document). The workshop intends to solicit additional comments on the issues and questions presented in the draft guidance during the open comment period.

DATES: The public workshop will be held on April 29, 2008, from 8 a.m. to 6 p.m. Participants are encouraged to arrive early to ensure time for parking, security screening, and registration before the meeting. Security screening will begin at 7 a.m., and registration will begin at 7:30 a.m. Please preregister by April 22, 2008, according to the instructions in section I.C of this document.

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ADDRESSES: The public conference will be held at the Food and Drug Administration, White Oak Campus, Bldg. 2, located at 10903 New Hampshire Ave., Silver Spring, MD 20993.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. The Public Workshop

A. Why Are We Holding This Public Workshop?

The purpose of the workshop is to discuss the draft guidance announced in the **Federal Register** of March 27, 2008 (73 FR 16311), and any issues that it may raise, and to solicit additional input on the issues and questions presented in this draft guidance. In addition, the purpose of this workshop is to discuss the Companion Document.

B. What Are the Topics We Intend To Address at the Workshop?

We hope to discuss a large number of issues at the workshop, including, but not limited to:

- How to characterize the drug substance, including chemistry, nonclinical systemic and local tissue pharmacology and toxicology, and how to evaluate potential for and consequences of systemic clinical exposure.

- How to characterize the drug-device combination product, including the chemical/physical/mechanical properties of the DES, the nonclinical local vascular and regional myocardial toxicology, and the clinical performance of the drug-stent combination.
- Regulatory considerations that are unique to DES combination products.
- Other issues and questions raised by the workshop attendees or others.

C. Is There a Fee and How Do I Register for the Workshop?

There is a modest fee to attend the workshop to defray the costs of meals provided and other expenses. The fee for the meeting for registrants from industry is $125, and the fee for government registrants is $75. Fees will be waived for invited speakers and panelists. The registration process will be handled by AdvaMed, which has extensive experience in planning, executing, and organizing educational meetings. Register online at *www.AdvaMed.org.* Although the facility is spacious, registration will be on a first-come, first-served basis. If you need special accommodations because of a disability, please contact Elizabeth Hillebrenner at least 7 days before the workshop.

D. Where Can I Find Out More About This Public Workshop?

Background information on the workshop, registration information, the agenda, information about lodging, and other relevant information will be posted, as it becomes available, on the Internet at: *www.AdvaMed.org* and *http://www.fda.gov/cdrh/dsma/workshop.html.*

II. Electronic Access

Persons with access to the Internet may obtain both the draft guidance document entitled "Coronary Drug-Eluting Stents: Nonclinical and Clinical Studies"and the Companion Document at: *http://www.fda.gov/cdrh/ode/guidance/6255.pdf.*

Dated: 4/18/2008
April 18, 2008.

Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

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