to estimate the extent of elevated blood-lead levels (BLLs) among children less than 6 years old. This is important because it will allow us to systematically track the management and follow-up of those children found to be poisoned with lead.

Our next objective for the continued use of this system is to examine potential sources of lead exposure. Although we've been successful in eliminating atmospheric lead with the use of unleaded gasoline and have continued to make strides in the elimination of household sources of lead commonly found in paint and dust, recent events have highlighted other potentially hidden sources of lead. This system will allow us to track the burden of such hidden sources and will help us eliminate such threats with the establishment of laws aimed at preventing the importation of such goods into our nation. The establishment of such laws will of course be a joint effort between several federal agencies; however, this surveillance system will help facilitate our efforts.

The final objective of this system is to facilitate the allocation of resources for lead poison prevention activities. The allocation of federal resources to State surveillance systems are based on reports of blood-lead tests from laboratories. Ideally, laboratories report results of all lead tests to the state health department. State health departments then send reports to CDC using de-identified data. It is from these reports that CDC is able to determine funding levels.

The use of both Childhood Lead Surveillance System and the ABLES Program will allow us to systematically track pockets of exposure to lead. It will also allow us to fully understand exposure potential and ways in which to prevent future sources of lead poisoning. Both systems are invaluable and will no doubt help us as we continue our stride in the elimination of lead poisoning in our nation.

There is no cost to respondents other than their time. The total estimated annualized burden hours are 656.

ESTIMATED ANNUALIZED BURDEN

Respondents	Number of respondents	Number of response per respondent	Average burden per response (in hrs.)	Total burden hours
State and Local Health Departments for Child Surveillance	42	4	2	336
State and Local Health Departments for Adult Surveillance	40	4	2	320
Total				656

Dated: April 18, 2008.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E8–8915 Filed 4–23–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0180]

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.

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: Ashley Boam, Center for Devices and Radiological Health, 9200 Corporate Blvd. (HFZ–400), Rockville, MD 20850, 240–276–3983 *ashley.boam@fda.hhs.gov* or Elizabeth Hillebrenner, Center for Devices and Radiological Health, 9200 Corporate Blvd. (HFZ–450), Rockville, MD, 20850, 240–276–4222, *elizabeth.hillebrenner@fda.hhs.gov*

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: April 18, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–8853 Filed 4–23–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee; Notice of Postponement of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is postponing the meeting of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee scheduled for May 16, 2008. The meeting was announced in the **Federal Register** of March 27, 2008 (73 FR 16315). FDA's Center for Devices and Radiological Health will further evaluate data relevant to the topic. A future meeting date will be announced in the **Federal Register**.

Contact Person: Michael Bailey, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4100, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512524. Please call the Information Line for up-to-date information on this meeting.

Dated: April 17, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–8845 Filed 4–23–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Commitment Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is required, under the Food and Drug Administration Modernization Act of 1997 (Modernization Act), to report annually in the **Federal Register** on the status of postmarketing study commitments made by applicants of approved drug and biological products. This is the agency's report on the status of the studies applicants have agreed to or are required to conduct.

FOR FURTHER INFORMATION CONTACT: Cathryn C. Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6464, Silver Spring, MD 20993–0002, 301–796–0700; or

Robert Yetter, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1400 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

Section 130(a) of the Modernization Act (Public Law 105–115) amended the Federal Food, Drug, and Cosmetic Act (the act) by adding a new provision requiring reports of certain postmarketing studies (section 506B of the act (21 U.S.C. 356b)) for human drug and biological products. Section 506B of the act provides FDA with additional authority to monitor the progress of a postmarketing study commitment that an applicant has been required or has agreed to conduct by requiring the applicant to submit a report annually providing information on the status of the postmarketing study commitment. This report must also include reasons, if any, for failure to complete the commitment. On December 1, 1999 (64 FR 67207), FDA published a proposed rule providing a framework for the content and format of the annual progress report. The proposed rule also clarified the scope of the reporting requirement and the timing for submission of the annual progress reports. The final rule, published on October 30, 2000 (65 FR 64607), modified annual report requirements for new drug applications (NDAs) and abbreviated new drug applications (ANDAs) by revising § 314.81(b)(2)(vii) (21 CFR 314.81(b)(2)(vii)). The rule also created a new annual reporting requirement for biologics license applications (BLAs) by establishing § 601.70 (21 CFR 601.70). These regulations became effective on April 30, 2001. The regulations apply only to human drug and biological products. They do not apply to animal drug or to biological products that also meet the definition of a medical device.

On September 27, 2007, the President signed Public Law 110–85, the Food and Drug Administration Amendments Act of 2007 (FDAAA). Section 901, in Title IX of FDAAA, creates a new section 505(o) of the act authorizing FDA to require certain studies and clinical trials for prescription drugs and biological products approved under section 505 of the act or section 351 of the Public Health Service Act. This new authority became effective on March 25, 2008. FDA is considering how this new authority will be integrated with postmarketing commitments. FDA expects that next year's report will reflect this integration.

Sections 314.81(b)(2)(vii) and 601.70 apply to postmarketing commitments made on or before enactment of the Modernization Act (November 21, 1997) as well as those made after that date. Sections 314.81(b)(2)(vii) and 601.70 require applicants of approved drug and