• 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Persons with access to the Internet may obtain both the draft guidance document entitled ''Coronary Drug-Eluting Stents: Nonclinical and Clinical Studies''and the Companion Document at: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