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Persons with access to the Internet may obtain both the draft guidance document entitled ''Coronary Drug-Eluting Stents: Nonclinical and Clinical Studies''and the Companion Document at: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

biological products to submit annually a report on the status of each clinical safety, clinical efficacy, clinical pharmacology, and nonclinical toxicology study that is required by FDA (e.g., accelerated approval clinical benefit studies) or that they have committed to conduct either at the time of approval or after approval of their NDA, ANDA, or BLA. The status of other types of postmarketing commitments (e.g., those concerning chemistry, manufacturing, production controls, and studies conducted on an applicant's own initiative) are not required to be reported under §§ 314.81(b)(2)(vii) and 601.70 and are not addressed in this report. It should be noted, however, that applicants are required to report to FDA on these commitments made for NDAs and ANDAs under § 314.81(b)(2)(viii).

According to the regulations, once a postmarketing study commitment has been made, an applicant must report on the progress of the commitment on the anniversary of the product's approval until the postmarketing study commitment is completed or terminated and FDA determines that the postmarketing study commitment has been fulfilled or that the postmarketing study commitment is either no longer feasible or would no longer provide useful information. The annual progress report must include a description of the postmarketing study commitment, a schedule for completing the study commitment, and a characterization of the current status of the study commitment. The report must also provide an explanation of the postmarketing study commitment's status by describing briefly the postmarketing study commitment's progress. A postmarketing study commitment schedule is expected to include the actual or projected dates for the following: (1) Submission of the study protocol to FDA, (2) completion of subject accrual or initiation of an animal study, (3) completion of the study, and (4) submission of the final study report to FDA. The postmarketing study commitment status must be described in the annual report according to the following definitions:

- Pending: The study has not been initiated (i.e., no subjects have been enrolled or animals dosed), but does not meet the criterion for delayed (i.e., the original projected date for initiation of subject accrual or initiation of animal dosing has not passed);
- Ongoing: The study is proceeding according to or ahead of the original schedule;
- Delayed: The study is behind the original schedule;
- Terminated: The study was ended before completion, but a final study report has not been submitted to FDA; or
- Submitted: The study has been completed or terminated, and a final study report has been submitted to FDA.

Databases containing information on postmarketing study commitments are maintained at the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). Information in this report covers any postmarketing study commitment that was made, in writing, at the time of approval or after approval of an application or a supplement to an application, including those required (e.g., to demonstrate clinical benefit of a product following accelerated approval) and those agreed to with the applicant. Information summarized in this report includes: (1) The number of applicants with open (uncompleted) postmarketing commitments, (2) the number of open postmarketing commitments, (3) the status of open postmarketing commitments as reported in § 314.81(b)(2)(vii) or § 601.70 annual reports, (4) the status of concluded postmarketing studies as determined by FDA, and (5) the number of applications with open postmarketing commitments for which applicants did not submit an annual report within 60 days of the anniversary date of U.S. approval.

Additional information about postmarketing study commitments made by applicants to CDER and CBER is provided on FDA's Web site at *http://www.fda.gov/cder/pmc*. Like this notice, the site does not list postmarketing study commitments containing proprietary information. It is FDA policy not to post information on the Web site until it has been reviewed for accuracy. The numbers published in this notice cannot be compared with the numbers resulting from searches of the Web site. This notice incorporates totals for all postmarketing study commitments in FDA databases, including those undergoing review for accuracy. The report in this notice will be updated annually while the Web site is updated quarterly (in January, April, July, and October).

II. Summary of Information From Postmarketing Study Progress Reports

This report summarizes the status of postmarketing commitments as of September 30, 2007. If a commitment did not have a schedule or a postmarketing progress report was not received, the commitment is categorized according to the most recent information available to the agency.

Data in table 1 are numerical summaries generated from FDA databases. The data are broken out according to application type (NDAs/ANDAs or BLAs).

TABLE 1.—SUMMARY OF POSTMARKETING STUDY COMMITMENTS (NUMBERS AS OF SEPTEMBER 30, 2007)

	NDAs/ANDAs (% of Total)	BLAs[1] (% of Total)
Applicants with open postmarketing commitments	136	54
Number of open postmarketing commitments	1,281	401
Status of open postmarketing commitments		
• Pending	911 (71%)	133 (33%)
Postmarketing commitment created within the last year (FY07)	165 (18%)	41 (31%)
Postmarketing commitment created within the past 2 years (FY06 and FY07)	361 (40%)	99 (74%)
Postmarketing commitment created within the past 3 years (FY05, FY06, and FY07)	489 (54%)	111 (83%)
• Ongoing	173 (14%)	98 (24%)
• Delayed	39 (3%)	86 (22%)

TABLE 1.—SUMMARY OF POSTMARKETING STUDY COMMITMENTS (NUMBERS AS OF SEPTEMBER 30, 2007)—Continued

	NDAs/ANDAs (% of Total)	BLAs[1] (% of Total)
• Terminated	1 (0.1%)	3 (1%)
• Submitted	157 (12%)	81 (20%)
Concluded studies (October 1, 2006—September 30, 2007)	133	26
• Commitment met	101 (76%)	21 (81%)
• Commitment not met	1 (<1%)	0
• Study no longer needed or feasible	31 (23%)	5 (19%)
Applications with open postmarketing commitments with annual reports due, but not submitted within 60 days of the anniversary date of U.S. approval	115 (37%)[2]	41 (51%)

[1] On October 1, 2003, FDA completed a consolidation of certain products formerly regulated by CBER into CDER. The previous association of BLA reviews only with CBER is no longer valid; BLAs are now received by both CBER and CDER. Fiscal year statistics for CDER BLA postmarketing study commitments will continue to be counted under BLA totals in this table.

[2] Note that this statistic counts all annual reports submitted more than 60 days after the anniversary date of U.S. approval as overdue, including reports that may have been submitted on a modified reporting schedule in accordance with prior FDA agreement. Of the applications categorized as having overdue annual reports using this definition, annual reports were subsequently submitted in FY06 for 115/115 (100 percent) of NDAs/ANDAs and 20/41 (49 percent) of BLAs.

Dated: April 15, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–9007 Filed 4–23–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[CFDA Number 93.224; HRSA–09–095, HRSA–09–096, HRSA–09–097, and HRSA–09–098]

Amendment to the Fiscal Year 2009 Service Area Competition—New and Competing Continuation Funding

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Change in application deadline and amendment of the available service areas.

SUMMARY: HRSA is announcing the reissuance of Fiscal Year 2009 Service Area Competition—New and Competing Continuation Funding (HRSA Announcement Numbers HRSA–09–095, HRSA–09–096, HRSA–09–097, and HRSA–09–098). The HRSA Electronic Handbook (EHB) application deadline for project periods beginning in November and December 2008 has been changed and the list of available service areas has been updated.

The new EHB application deadline for HRSA–09–095 is May 9, 2008. (The grants.gov application deadline of April 7, 2008 remains the same.) All other requirements of HRSA–09–095 remain the same. Please see the chart on pages 6 and 7 of the guidance for a complete listing of all application deadlines.

In addition, corrections to two service areas listed in the Service Area Competition guidance have been made. In Appendix F of the guidance, Bismarck, ND, is *incorrectly* listed as an available service area in fiscal year (FY) 2009. The correct service area that is currently available in FY 2009 is Beulah, ND. Also, Clay, WV, is *incorrectly* listed as an available service area in FY 2009. The correct service area that is currently available in FY 2009 is Blacksville, WV. Bismarck, ND and Clay, WV, are not available service areas for the FY 2009 Service Area Competition. For a complete listing of all available service areas for the FY 2009 Service Area Competition funding opportunity, please see Appendix F of the guidance.

DATES: The effective date of this amended Agency guidance is April 24, 2008.

Background: HRSA administers the Health Center Program, which supports more than 4,000 health care delivery sites, including community health centers, migrant health centers, health care for the homeless centers, and public housing primary care centers. Health centers serve clients that are primarily low-income and minorities, and deliver comprehensive, culturally competent, quality primary health care services to patients regardless of their ability to pay. Charges for health care services are set according to income.

FOR FURTHER INFORMATION CONTACT: For questions regarding this notice, please contact Nicole Amado in the Office of Policy and Program Development, Bureau of Primary Health Care, HRSA, at 301–594–4300 or *Nicole.Amado@hrsa.hhs.gov.*

Dated: April 17, 2008.

Elizabeth M. Duke,

Administrator.

[FR Doc. E8–9009 Filed 4–23–08; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Committee on Rural Health and Human Services; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given that the following committee will convene its fifty-ninth meeting.

Name: National Advisory Committee on Rural Health and Human Services.

Dates and Times: June 2, 2008, 9 a.m.–4:30 p.m. June 3, 2008, 8:45 a.m.–5:15 p.m. June 4, 2008, 8:15 a.m.–10:30 a.m.

Place: Siena Hotel, 1505 East Franklin Street, Chapel Hill, NC 27514. Phone: 919–929–4000.

Status: The meeting will be open to the public.

Purpose: The National Advisory Committee on Rural Health and Human Services provides advice and recommendations to the Secretary with respect to the delivery, research,