

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

	NDA/ANDAs (% of Total)	BLAs <sup>1</sup> (% 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%) <sup>2</sup>	41 (51%)

<sup>1</sup> 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 The previous association of BLA reviews only with CBER is no longer valid; BLAs are now received by both CBER and CDER.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 post-marketing study commitments will continue to be counted under BLA totals in this table.

<sup>2</sup> 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.*

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## 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](mailto:Nicole.Amado@hrsa.hhs.gov).

Dated: April 17, 2008.

**Elizabeth M. Duke,**  
*Administrator.*

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## 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,