

reports, (4) the status of concluded postmarketing studies as determined by FDA, and (5) the number of open postmarketing commitments for which FDA did not receive an annual report.

Additional information about postmarketing study commitments made by sponsors to CDER and CBER are provided on FDA's Web site at <http://www.fda.gov/cder>. 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 information currently

available on the site includes only postmarketing study commitments made since January 1, 1991. 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 made prior to 1991 as well as those undergoing review for accuracy. The report in this notice will be updated annually while the Web site will be updated quarterly (in April, July, October, and January).

II. Summary of Information From Postmarketing Study Progress Reports

This report summarizes the status of postmarketing commitments as of September 30, 2002. If a commitment did not have a schedule and 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 TO CBER AND CDER
(NUMBERS AS OF SEPTEMBER 30, 2002)

	NDAs/ANDAs (% of total)	BLAs (% of total)
Applicants with open postmarketing commitments	126	44
Number of open postmarketing commitments	1,339	223
Status of open postmarketing commitments		
• Pending	820 (61%)	67 (30%)
• Ongoing	285 (21%)	102 (46%)
• Delayed	25 (2%)	17 (8%)
• Terminated	8 (1%)	2 (1%)
• Submitted	201 (15%)	35 (16%)
Concluded studies	349	52
• Commitment met	240 (69%)	47 (90%)
• Commitment not met	0 (0%)	1 (2%)
• Study no longer needed or feasible	109 (31%)	4 (8%)
Open postmarketing commitments with annual report due but not received	289 (22%)	77 (35%)

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Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

HRSA-03-87 Notice of Cooperative Agreement to Plan, Develop, Implement, and Operate a Continuing Clinical Education Program in the Pacific Basin (CPAC) CFDA Number 93.884

The Health Resources and Services Administration (HRSA) announces that applications will be accepted for a

Cooperative Agreement for fiscal year (FY) 2003 to Plan, Develop, Implement, and Operate a Continuing Clinical Education Program in the Pacific Basin.

The purpose of this Cooperative Agreement is to plan, develop, implement and operate a continuing clinical education (CCE) program in the U.S.-Associated Pacific Islands. Six island jurisdictions comprise the U.S.-Associated Pacific Basin: American Samoa, the Commonwealth of the North Mariana Islands, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands and the Republic of Palau. A cooperative agreement will be awarded to assist the eligible entity to develop, implement and operate a CCE program in the U.S.-Associated Pacific Basin. The goal is to meet the needs of the health care workforce in all six island jurisdictions by providing

training to a full range of primary care and allied health providers emphasizing cultural competency and distance learning; developing a needs assessment to identify the specific educational needs and develop curricula and recruit faculty; demonstrate linkages and relationships within all six island jurisdictions; and establish an advisory board with all six island jurisdictions represented.

The Pacific Basin health care workforce is comprised of Pacific Basin Medical Officers and other primary care providers (family physicians, general internists, general pediatricians, dental professionals, physician assistants, nurses, health assistants, and allied health workers). Allied Health professionals include health professionals who have received a certificate, an associate's degree, a