clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0509. The approval expires on October 31, 2003. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: May 15, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–12725 Filed 5–20–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0170]

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 sponsors of approved drug and biological products. This is the agency's first report on the status of the study commitments that sponsors have agreed to conduct and for which an annual status report on the study has been received by FDA.

FOR FURTHER INFORMATION CONTACT: Kim Colangelo, Center for Drug Evaluation and Research (HFD–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–3937; or Robert Yetter, Center for Biologics Evaluation and Research (HFM–25), 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 (section 506B of the act (21 U.S.C. 356b)) requiring reports of postmarketing studies for human drugs and biological products. Section 506B 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 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 establishing § 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 26, 2001. The regulations apply only to human drugs, including biological drugs. They do not apply to animal drugs or to licensed biological products that also meet the definition of a medical device.

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 drugs 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, BLA, or supplement. 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: (1) Submission of the study protocol to FDA, (2) completion of patient 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, but does not meet the criterion for delayed;
- 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 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%)

Dated: May 12, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–12720 Filed 5–20–03; 8:45 am]

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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