order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the FD&C Act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from April 1, 2011, through June 30, 2011. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM APRIL 1, 2011, THROUGH JUNE 30, 2011

PMA No./Docket No.	Applicant	Trade name	Approval date
P050050 FDA–2011–M–0323	Small Bone Innovations, Inc	Scandinavian total ankle replacement system	May 27, 2009.
P060004(S1) FDA–2011–M–0256	Carl Zeiss Meditec, Inc	Meditec MEL 80 excimer laser system	March 28, 2011.
P100040 FDA–2011–M–0257	Medtronic Vascular	Valiant thoracic stent graft system	April 1, 2011.
H100002 FDA–2011–M–0241	NeuroVasx, Inc	cPAX aneurysm treatment system	April 1, 2011.
P100018 FDA–2011–M–0284	Chestnut Medical Technologies, Inc.	Pipeline embolization device	April 6, 2011.
P100034 FDA–2011–M–0295	NovoCure, Ltd	NovoCure Ltd.'s NovoTTF–100A treatment kit	April 8, 2011.
P100020 FDA–2011–M–0300	Roche Molecular Systems, Inc	cobas HPV test	April 19, 2011.
P100029 FDA–2011–M–0296	St. Jude Medical, Inc	Trifecta heart valve	April 20, 2011.
P100023 FDA–2011–M–0342	Boston Scientific Corp	ION paclitaxel-eluting coronary stent system (mono-rail and over-the-wire systems).	April 22, 2011.
P930014 (S45) FDA–2011–M–0338.	Alcon Research, Ltd	AcrySof toric IOL and AcrySof IQ toric IOL	May 3, 2011.
P040012 (S34) FDA–2011–M–0343.	Abbott Vascular, Inc	RX Acculink carotid stent system	May 6, 2011.
P090028 FDA–2011–M–0348	Ortho-Clinical Diagnostics, Inc	Vitros immunodiagnostic products HBeAg reagent pack/products HBeAg calibrator/products HBe controls.	May 11, 2011.
P100017 FDA–2011–M–0349	Abbott Molecular, Inc	Abbott RealTi*m*e HCV, Abbott RealTi*m*e HCV amplification reagent kit, Abbott RealTi*m*e HCV control kit, Abbott RealTi*m*e HCV calibrator kit, and optional UNG Uracil-N-glycosylase.	May 17, 2011.
P100013 FDA–2011–M–0430	Cordis Corp	Cordis ExoSeal vascular closure device	May 19, 2011.
P070015 (S54) FDA–2011–M–0431.	Abbott Vascular	Xience nano everolimus-eluting coronary stent system and Promus everolimus-eluting coronary stent system.	May 24, 2011.
P100014 FDA–2011–M–0445	Oceana Therapeutics, Inc	Solesta injectable gel	May 27, 2011.
P090002 FDA–2011–M–0470	Depuy Orthopaedics, Inc	Pinnacle complete acetabular hip system	June 13, 2011.
P100027 FDA–2011–M–0472	Ventana Medical Systems, Inc	INFORM HER2 dual ISH DNA probe cocktail	June 14, 2011.
P100031 FDA–2011–M–0502	Roche Diagnostics Corp	Elecsys anti-HBc immunoassay and Elecsys PreciControl anti-HBc for use on the modular Analytics E170 immunoassay analyzer.	June 22, 2011.
P100032 FDA–2011–M–0503	Roche Diagnostics Corp	Elecsys anti-HBc immunoassay and Elecsys PreciControl anti-HBc for use on the Elecsys 2010 immunoassay analyzer.	June 27, 2011.

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cdrh/pmapage.html*.

Dated: July 29, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–19734 Filed 8–3–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0332]

Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: Under the Food and Drug Administration Modernization Act of 1997 (Modernization Act), the Food and Drug Administration (FDA) is required to report annually in the **Federal Register** on the status of postmarketing requirements and commitments required of, or agreed upon by, holders of approved drug and biological products. This notice is the Agency's report on the status of the studies and clinical trials that applicants have agreed to, or are required to, conduct.

FOR FURTHER INFORMATION CONTACT: Beth Duvall-Miller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6466, Silver Spring, MD 20993–0002, 301–796–0700; or Stephen Ripley, Center for

Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1400 Rockville Pike, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Modernization Act

Section 130(a) of the Modernization Act (Pub. L. 105–115) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding a new provision requiring reports of certain postmarketing studies, including clinical trials, for human drug and biological products (section 506B of the FD&C Act (21 U.S.C. 356b)). Section 506B of the FD&C Act provides FDA with additional authority to monitor the progress of a postmarketing study or clinical trial that an applicant has been required to, or has agreed to, conduct by requiring the applicant to submit a report annually providing information on the status of the postmarketing study/clinical trial. This report must also include reasons, if any, for failure to complete the study/clinical trial. These studies and clinical trials are intended to further define the safety, efficacy, or optimal use of a product, and therefore play a vital role in fully characterizing the product.

Under the Modernization Act, commitments to conduct postmarketing studies or clinical trials included both studies/clinical trials that applicants agreed to conduct, as well as studies/clinical trials that applicants were required to conduct under FDA regulations.[1]

B. The Food and Drug Administration Amendments Act of 2007

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, created a new section 505(o) of the FD&C Act authorizing FDA to require certain studies and clinical trials for human drug and biological products approved under section 505 of the FD&C Act or section 351 of the Public Health Service Act. Under FDAAA, FDA has been given additional authority to require applicants to conduct and report on postmarketing studies and clinical trials to assess a known serious risk, assess signals of serious risk, or identify an unexpected serious risk related to the use of a product. This new authority became effective on March 25, 2008. FDA may now take enforcement action against applicants who fail to conduct studies and clinical trials required under FDAAA, as well as studies and clinical trials required under FDA regulations (see sections 505(o)(1), 502(z), and 303(f)(4) of the FD&C Act (21 U.S.C. 355(o)(1), 352(z), and 333(f)(4))).

Although regulations implementing the Modernization Act postmarketing authorities use the term ''postmarketing commitment'' to refer to both required studies and studies applicants agree to conduct, in light of the new authorities enacted in FDAAA, FDA has decided it is important to distinguish between enforceable postmarketing requirements and unenforceable postmarketing commitments. Therefore, in this notice and report, FDA refers to studies/clinical trials that an applicant is required to conduct as ''postmarketing requirements'' (PMRs) and studies/clinical trials that an applicant agrees to but is not required to conduct as ''postmarketing commitments'' (PMCs). Both are addressed in this notice and report.

C. FDA's Implementing Regulations

On October 30, 2000 (65 FR 64607), FDA published a final rule implementing section 130 of the Modernization Act. This rule modified the 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). The rule described the content and format of the annual progress report, and clarified the scope of the reporting requirement and the timing for submission of the annual progress reports. The rule became effective on April 30, 2001. The regulations apply only to human drug and biological products approved under NDAs, ANDAs, and BLAs. They do not apply to animal drugs or to biological products regulated under the medical device authorities.

The reporting requirements under §§ 314.81(b)(2)(vii) and 601.70 apply to PMRs and PMCs made on or before the enactment of the Modernization Act (November 21, 1997), as well as those made after that date. Therefore, studies and clinical trials required under FDAAA are covered by the reporting requirements in these regulations.

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/clinical trial either required by FDA 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 PMCs concerning chemistry, manufacturing, and production controls and the status of other studies/clinical trials 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). Furthermore, section 505(o)(3)(E) of the FD&C Act, as amended by FDAAA, requires that applicants report periodically on the status of each required study/clinical trial and each study/clinical trial ''otherwise undertaken * * * to investigate a safety issue * * *.''

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

- *Pending:* The study/clinical trial has not been initiated *(i.e.,* no subjects have been enrolled or animals dosed), but does not meet the criteria for delayed (*i.e.,* the original projected date for initiation of subject accrual or

[1] Before passage of the Food and Drug Administration Amendments Act of 2007 (FDAAA), FDA could require postmarketing studies and clinical trials under the following circumstances: To verify and describe clinical benefit for a human drug approved in accordance with the accelerated approval provisions in section 506(b)(2)(A) of the FD&C Act (21 CFR 314.510 and 601.41); for a drug approved on the basis of animal efficacy data because human efficacy trials are not ethical or feasible (21 CFR 314.610(b)(1) and 601.91(b)(1)); and for marketed drugs that are not adequately labeled for children under section 505B of the FD&C Act (Pediatric Research Equity Act (21 U.S.C. 355c; Pub. L. 108–155)).

initiation of animal dosing has not passed);

- *Ongoing:* The study/clinical trial is proceeding according to or ahead of the original schedule;
- *Delayed:* The study/clinical trial is behind the original schedule;
- *Terminated:* The study/clinical trial was ended before completion, but a final report has not been submitted to FDA; or
- *Submitted:* The study/clinical trial has been completed or terminated, and a final report has been submitted to FDA.

Databases containing information on PMRs/PMCs are maintained at the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER).

II. Summary of Information From Postmarketing Status Reports

This report, published to fulfill the annual reporting requirement under the Modernization Act, summarizes the status of PMRs and PMCs as of September 30, 2010. If a requirement or commitment did not have a schedule, or a postmarketing progress report was not received in the previous 12 months, the PMR/PMC is categorized according to the most recent information available to the Agency.[2]

Information in this report covers any PMR/PMC that was made, in writing, at the time of approval or after approval of an application or a supplement to an application, including PMRs required under FDAAA (section 505(o)(3) of the FD&C Act), PMRs required under FDA regulations (*e.g.,* PMRs required to demonstrate clinical benefit of a product following accelerated approval (see footnote 1 of this document)), and PMCs agreed to by the applicant.

Information summarized in this report includes the following: (1) The number of applicants with open (uncompleted) PMRs/PMCs, (2) the number of open PMRs/PMCs, (3) the status of open PMRs/PMCs as reported in § 314.81(b)(2)(vii) or § 601.70 annual reports, (4) the status of concluded PMRs/PMCs as determined by FDA, and (5) the number of applications with open PMRs/PMCs for which applicants did not submit an annual report within 60 days of the anniversary date of U.S. approval.

Additional information about PMRs/PMCs submitted by applicants to CDER and CBER is provided on FDA's Web site at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/default.htm.* Neither the Web site nor this notice include information about PMCs concerning chemistry, manufacturing, and controls. It is FDA policy not to post information on the Web site until it has been reviewed for accuracy. Numbers published in this notice cannot be compared with the numbers resulting from searches of the Web site because this notice incorporates totals for all PMRs/PMCs in FDA databases, including PMRs/PMCs undergoing review for accuracy. In addition, the report in this notice will be updated annually while the Web site is updated quarterly (*i.e.,* in January, April, July, and October).

Many applicants have more than one approved product and for many products there is more than one PMR or PMC. Specifically, there were 164 unique applicants with 233 NDAs/ANDAs that had open PMRs/PMCs. There were 69 unique applicants with 87 BLAs that had open PMRs/PMCs.

Annual status reports are required to be submitted for each open PMR/PMC within 60 days of the anniversary date of U.S. approval of the original application. In fiscal year 2010 (FY10), 20 percent (36/184) of NDA/ANDA and 36 percent (31/87) of BLA annual status reports were not submitted within 60 days of the anniversary date of U.S. approval of the original application. Of the annual status reports due but not submitted on time, 100 percent of the NDA/ANDA and 52 percent (16/31) of the BLA reports were submitted before the close of FY10 (September 30, 2010).

Most PMRs are progressing on schedule (91 percent for NDAs/ANDAs; 88 percent for BLAs). Most PMCs are also progressing on schedule (84 percent for NDAs/ANDAs; 77 percent for BLAs). Most of the PMCs that are currently listed in the database were developed before the postmarketing requirements section of FDAAA took effect.[3]

III. About This Report

This report provides six separate summary tables. The tables in this document distinguish between PMRs and PMCs and between on-schedule and off-schedule PMRs and PMCs according to the original schedule milestones. On-schedule PMRs/PMCs are categorized as pending, ongoing, or submitted. Off-schedule PMRs/PMCs that have missed one of the original milestone dates are categorized as delayed or terminated. The tables include data as of September 30, 2010.

Table 1 of this document provides an overall summary of the data on all PMRs and PMCs. Tables 2 and 3 of this document provide detail on PMRs. Table 2 of this document provides additional detail on the status of on-schedule PMRs.

Table 1 of this document shows that most PMRs (91 percent for NDAs/ANDAs and 88 percent for BLAs) and most PMCs (84 percent for NDAs/ANDAs and 77 percent for BLAs) are on schedule. Overall, of the PMRs that are pending (*i.e.,* have not been initiated), 92 percent were created within the past 3 years. Table 2 of this document shows that 53 percent of pending PMRs for drug and biological products are in response to the Pediatric Research and Equity Act (PREA), under which FDA requires sponsors to study new drugs, when appropriate, for pediatric populations. Under section 505B(a)(3) of the FD&C Act, the initiation of these studies generally is deferred until required safety information from other studies has first been submitted and reviewed. PMRs for products approved under the animal efficacy rule (21 CFR 314.600 for drugs; 21 CFR 601.90 for biological products) can be conducted only when the product is used for its indication as a counterterrorism measure. In the absence of a public health emergency, these studies/clinical trials will remain pending indefinitely. The next largest category of pending PMRs for drug and biological products (45 percent) comprises those studies/clinical trials required by FDA under FDAAA, which became effective on March 25, 2008.

Table 3 of this document provides additional detail on the status of off-schedule PMRs. The majority of off-schedule PMRs (which account for 9 percent of the total for NDAs/ANDAs and 12 percent for BLAs) are delayed according to the original schedule milestones (96 percent (47/49) for NDAs/ANDAs; 94 percent (17/18) for BLAs). In certain situations, the original schedules may have been adjusted for unanticipated delays in the progress of the study/clinical trial (*e.g.,* difficulties with subject enrollment in a trial for a marketed drug or need for additional time to analyze results). In this report, study/clinical trial status reflects the status in relation to the original study/clinical trial schedule regardless of whether FDA has acknowledged that additional time may be required to complete the study/clinical trial.

[2] Although the data included in this report do not include a summary of reports that applicants have failed to file by their due date, the Agency notes that it may take appropriate regulatory action in the event reports are not filed on a timely basis.

[3] There are existing PMCs established before FDAAA that might meet current FDAAA standards for required safety studies/clinical trials under section 505(o)(3)(B) of the FD&C Act. Under section 505(o)(3)(c) of the FD&C Act, the Agency may convert pre-existing PMCs into PMRs if it becomes aware of new safety information.

Tables 4 and 5 of this document provide additional detail on the status of PMCs. Table 4 of this document provides additional detail on the status of on-schedule PMCs. Pending PMCs comprise 50 percent (201/399) of the on-schedule NDA/ANDA PMCs and 28 percent (66/236) of the on-schedule BLA PMCs.

Table 5 of this document provides additional details on the status of off-schedule PMCs. The majority of off-schedule PMCs (which account for 16 percent for NDAs/ANDAs and 23 percent for BLAs) are delayed according to the original schedule milestones (91 percent (67/74) for NDAs/ANDAs; 97 percent (69/71) for BLAs). As noted previously in this document, this report reflects the original due dates for study/clinical trial results and does not reflect discussions between the Agency and the sponsor regarding studies/clinical trials that may require more time for completion.

Table 6 of this document provides details about PMRs and PMCs that were concluded in the previous year. The majority of concluded PMRs and PMCs were fulfilled (57 percent of NDA/ANDA PMRs and 40 percent of BLA PMRs; 85 percent of NDA/ANDA PMCs and 84 percent of BLA PMCs).

TABLE 1—SUMMARY OF POSTMARKETING REQUIREMENTS AND COMMITMENTS

[Numbers as of September 30, 2010]

	NDA/ANDA (% of total PMR or % of total PMC)	BLA (% of total PMR or % of total PMC) [1]
Number of open PMRs	526	149
On-schedule open PMRs (see table 2 of this document)	477 (91%)	131 (88%)
Off-schedule open PMRs (see table 3 of this document)	49 (9%)	18 (12%)
Number of open PMCs	473	307
On-schedule open PMCs (see table 4 of this document)	399 (84%)	236 (77%)
Off-schedule open PMCs (see table 5 of this document)	74 (16%)	71 (23%)

[1] On October 1, 2003, FDA completed a consolidation of certain therapeutic products formerly regulated by CBER into CDER. Consequently, CDER now reviews many BLAs. Fiscal year statistics for postmarketing requirements and commitments for BLAs reviewed by CDER are included in BLA totals in this table.

TABLE 2—SUMMARY OF ON-SCHEDULE POSTMARKETING REQUIREMENTS

[Numbers as of September 30, 2010]

On-schedule open PMRs	NDA/ANDA (% of total PMR)	BLA (% of total PMR) [1]
Pending (by type):		
Accelerated approval	7	2
PREA [2]	217	27
Animal efficacy [3]	1	0
FDAAA safety (since March 25, 2008)	145	62
Total	370 (70%)	91 (61%)
Ongoing:		
Accelerated approval	12	7
PREA [2]	26	2
Animal efficacy [3]	0	0
FDAAA safety (since March 25, 2008)	28	22
Total	66 (13%)	31 (21%)
Submitted:		
Accelerated approval	5	3
PREA [2]	22	4
Animal efficacy [3]	0	0
FDAAA safety (since March 25, 2008)	14	2
Total	41 (8%)	9 (6%)
Combined total	477 (91%)	131 (88%)

[1] See note 1 for table 1 of this document.

[2] Many PREA studies have a pending status. PREA studies are usually deferred because the product is ready for approval in adults. Initiation of these studies also may be deferred until additional safety information from other studies has first been submitted and reviewed.

[3] PMRs for products approved under the animal efficacy rule (21 CFR 314.600 for drugs; 21 CFR 601.90 for biological products) can be conducted only when the product is used for its indication as a counterterrorism measure. In the absence of a public health emergency, these studies/clinical trials will remain pending indefinitely.

TABLE 3—SUMMARY OF OFF-SCHEDULE POSTMARKETING REQUIREMENTS

[Numbers as of September 30, 2010]

Off-schedule open PMRs	NDA/ANDA (% of total PMR)	BLA (% of total PMR) [1]
Delayed:		
Accelerated approval	5	2
PREA	39	11
Animal efficacy	1	0
FDAAA safety (since March 25, 2008)	2	4
Total	47 (9%)	17 (11%)
Terminated	2 (0.4%)	1 (0.7%)
Combined total	49 (9%)	18 (12%)

[1] See note 1 for table 1 of this document.

TABLE 4—SUMMARY OF ON-SCHEDULE POSTMARKETING COMMITMENTS

[Numbers as of September 30, 2010]

On-schedule open PMCs	NDA/ANDA (% of total PMC)	BLA (% of total PMC) [1]
Pending	201 (42%)	66 (21%)
Ongoing	87 (18%)	95 (31%)
Submitted	111 (23%)	75 (24%)
Combined total	399 (84%)	236 (77%)

[1] See note 1 for table 1 of this document.

TABLE 5—SUMMARY OF OFF-SCHEDULE POSTMARKETING COMMITMENTS

[Numbers as of September 30, 2010]

Off-schedule open PMCs	NDA/ANDA (% of total PMC)	BLA (% of total PMC) [1]
Delayed	67 (14%)	69 (22%)
Terminated	7 (1%)	2 (0.7%)
Combined total	74 (16%)	71 (23%)

[1] See note 1 for table 1 of this document.

TABLE 6—SUMMARY OF CONCLUDED POSTMARKETING REQUIREMENTS AND COMMITMENTS (OCTOBER 1, 2009 TO OCTOBER 1, 2010)

	NDA/ANDA (% of total)	BLA (% of total) [1]
Concluded PMRs:		
Requirement met (fulfilled)	25 (57%)	4 (40%)
Requirement not met (released and new revised requirement issued)	10 (23%)	0
Requirement no longer feasible or product withdrawn (released)	9 (20%)	6 (60%)
Total	44	10
Concluded PMCs:		
Commitment met (fulfilled)	174 (85%)	51 (84%)
Commitment not met (released and new revised requirement/commitment issued)	25 (12%)	1 (2%)
Commitment no longer feasible or product withdrawn (released)	5 (2%)	9 (15%)
Total	204	61

[1] See note 1 for table 1 of this document.

Dated: August 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–19806 Filed 8–3–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 76 FR 45584–45585 dated July 29, 2011).

This notice reflects organizational changes to the Health Resources and Services Administration. Specifically, this notice updates the Division of Vaccine Injury Compensation (RR4) functional statement to better align functional responsibility, improve the management and delivery of information technology services, improve management and administrative efficiencies, and optimize use of available staff resources within the Healthcare Systems Bureau (RR).

Chapter RR—Healthcare Systems Bureau

Section RR–10, Organization

Delete in its entirety and replace with the following:

The Healthcare Systems Bureau (RR) is headed by the Associate Administrator, who reports directly to the Administrator, Health Resources and Services Administration. The Healthcare Systems Bureau includes the following components:

(1) Office of the Associate Administrator (RR);

(2) Division of Transplantation (RR1);

(3) Division of Health Facilities (RR9);

(4) Division of Vaccine Injury Compensation (RR4); and

(5) Office of Pharmacy Affairs (RR7).

Section RR–20, Functions

(1) Delete the functional statement for the Division of Vaccine Injury Compensation (RR4) and replace in its entirety.

Division of Vaccine Injury Compensation (RR4)

The Division of Vaccine Injury Compensation (DVIC), on behalf of the Secretary of Health and Human Services (HHS), administers all statutory authorities related to the operation of the National Vaccine Injury Compensation Program (VICP) by: (1) Evaluating petitions for compensation filed under the VICP through medical review and assessment of compensability for all complete claims; (2) processing awards for compensations made under the VICP; (3) promulgating regulations to revise the Vaccine Injury Table; (4) providing professional and administrative support to the Advisory Commission on Childhood Vaccines (ACCV); (5) developing and maintaining all automated information systems necessary for program implementation; (6) providing and disseminating program information; (7) maintaining a working relationship with the Department of Justice (DOJ) and the U.S. Court of Federal Claims (the Court) in the administration and operation of the VICP; (8) providing management, direction, budgetary oversight, coordination, and logistical support for the Medical Expert Panel (MEP) contracts as well as Clinical Reviewer Contracts; (9) maintaining responsibility for activities related to the ACCV, the development of policy, regulations, budget formulation, and legislation, including the development and renewal of the ACCV charter and action memoranda to the Secretary, and the analysis of the findings and proposals of the ACCV; (10) developing, reviewing, and analyzing pending and new legislation relating to program changes, new initiatives, the ACCV, and changes to the Vaccine Injury Table, in coordination with the Office of the General Counsel (OGC); (11) providing programmatic outreach efforts to maximize public exposure to private and public constituencies; (12) providing submission of special reports to the Secretary of HHS, the Office of Management and Budget, the Congress, and other governmental bodies; and (13) providing the coordination of ACCV travel, personnel, meeting sites, and its agenda.

Section RR–30, Delegations of Authority

All delegations of authority and re-delegations of authority made to HRSA officials that were in effect immediately prior to this reorganization, and that are consistent with this reorganization, shall continue in effect pending further re-delegation.

This reorganization is effective upon date of signature.

Dated: July 29, 2011.

Mary K. Wakefield,

Administrator.

[FR Doc. 2011–19804 Filed 8–3–11; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Expediting Research Tools to NIH Licensees Through the Use of Pay.gov for Rapid Processing of Royalty Payments

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: NIH licensees can now expedite the receipt of research tools through the use of Pay.gov for rapid processing of their royalty payments.

SUPPLEMENTARY INFORMATION: With its introduction earlier this year, NIH licensees have found that using the new royalty payment site within Pay.gov expedites processing times for shipment of their research tools licensed from the NIH and FDA intramural research programs. The value of such time savings to corporate R&D programs is not trivial since waiting too long to secure research materials or tools can delay or sink a critical drug development program or other business venture. By eliminating the need for bank checks, the bank-to-bank transfer system at Pay.gov has shortened the processing time for research tool and other license agreements from several months down to a day or less. For example, a recent transaction for baculovirus vectors at NIH was indeed processed in a single afternoon allowing for almost instantaneous release of the licensed materials from the inventors laboratory.

Informal comments that NIH has received to date from licensees who have started to use Pay.gov for their royalty payments include: ''For Pay.gov, it's easy, convenient and fast, I guess that's what I experienced.'', ''It literally only took me about 5 minutes after reading the email/letter to process payment. Great service!'' and ''I just completed sending all the MAR payments and it was great! I am glad I decided to try the system.''

Pay.gov itself is a multifaceted web-based application allowing anyone to make Automated Clearing House (ACH) payments to government agencies by debit from a checking or savings account. Pay.gov is open 24–7, and is