## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2014–N–0001]**

### 2014 Medical Countermeasures Initiative Regulatory Science Symposium

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following meeting: 2014 Medical Countermeasures initiative (MCMi) Regulatory Science Symposium. The symposium is intended to provide a forum for the exchange of scientific ideas for medical countermeasure development and evaluation, communicate progress on regulatory science efforts related to the development and advancement of medical countermeasures, facilitate innovative directions, and inform stakeholders on medical countermeasure-related scientific progress and accomplishments.

*Date and Time:* This symposium will be held on June 2 and 3, 2014, from 8 a.m. to 5 p.m. Persons interested in attending the symposium in person or viewing via Web cast must register by May 23, 2014, at 5 p.m. EST.

*Location:* The symposium will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

*Contact:* Rakesh Raghuwanshi, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4283, 301–796–4769, FAX: 301–847–8615, email: *AskMCMi@fda.hhs.gov.*

*Registration:* If you wish to attend the symposium or view via Web cast, you must register at *http://www.fda.gov/medicalcountermeasures* by May 23, 2014, at 5 p.m. EST. When registering, you must provide the following information: (1) Your name, (2) title, (3) company or organization (if applicable), and (4) email address.

There is no fee to register for the symposium and registration will be on a first-come, first-served basis. Early registration is recommended because seating is limited. If you need special accommodations due to a disability, please enter pertinent information in the ''Notes'' section of the electronic registration form when you register.

Dated: February 11, 2014.

**Peter Lurie,**

*Acting Associate Commissioner for Policy and Planning.*

[FR Doc. 2014–03358 Filed 2–14–14; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2014–N–0006]**

### 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 (FDAMA), 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:** Cathryn C. Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6484, Silver Spring, MD 20993–0002, 301–796–0700; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852, 301–827–6210.

**SUPPLEMENTARY INFORMATION:**

## I. Background

### *A. The Food and Drug Administration Modernization Act*

Section 130(a) of FDAMA (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 FDAMA, 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 (42 U.S.C. 262). 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 FDAMA postmarketing authorities use

[1] Before passage of 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; Pub. L. 108–155).

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 FDAMA. 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 regulations became effective on April 30, 2001 (66 FR 10815). 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 FDAMA (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[2] 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 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.

[2] Some applicants have requested and been granted by FDA alternate annual reporting dates to facilitate harmonized reporting across multiple applications.

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 FDAMA, summarizes the status of PMRs and PMCs as of September 30, 2012. 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.[3]

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 PMRs/PMCs, (2) the number of open PMRs/PMCs, (3) FDA-verified status of open PMRs/PMCs 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 for which an annual report was expected, but was not submitted within 60 days of the anniversary date of U.S. approval or an alternate reporting date that has been granted by FDA.[4]

Additional information about PMRs/PMCs is provided on FDA's Web site at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PostmarketingPhaseIVCommitments/default.htm.* Neither the Web site nor this notice include information about PMCs concerning chemistry, manufacturing, and controls. It is FDA

[3] 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.

[4] The type of information included in this report is the same as in previous ones. However, as a result of improved data capture and refinement of analytical methods, some values in the fiscal year (FY) 2012 report are notably different from those reported in the previous reports. FDA intends to use the data capture and analytical methods applied to the FY2012 report in future annual reports. For clarity and comparison purposes, relevant data for the FY2012 report are provided using both the updated and previously used methods (see footnotes 5, 7, and 8).

policy not to post information on the Web site until it has been verified and reviewed for suitability for public disclosure. 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 status information reported in this notice will be updated annually while the Web site is updated quarterly (i.e., in January, April, July, and October).

An applicant may have multiple approved products, and an approved product may have multiple PMRs and/or PMCs. As of September 30, 2012, there were 172 unique applicants with 1,069 open PMRs/PMCs under 476 unique NDAs/ANDAs.[5] For BLAs, there were 72 unique applicants with 430 open PMRs/PMCs under 101 unique applications.

Applicants must submit an annual status report on the progress of each open PMR/PMC within 60 days of the anniversary date of U.S. approval of the original application or an alternate reporting date that has been granted by FDA. There were 432 NDAs/ANDAs with an annual status report due in fiscal year (FY) 2012.[6] Of the 432 annual status reports due, 61 percent (264/432) were received on time;[7] 19 percent (82/432) were received, but not on time; and 20 percent (86/432) were not received at any time during FY2012.[8]

For BLAs, there were 101 annual status reports expected in FY2012. Of those expected, 68 percent (69/101) were received on time; 12 percent (12/101) were received, but not on time; and 20 percent (20/101) were not received at any time during FY2012.

## 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, 2012.

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 open PMRs (81 percent for NDAs/ANDAs and 83 percent for BLAs) and most open PMCs (73 percent for NDAs/ANDAs and 76 percent for BLAs) are progressing on schedule (i.e., are not delayed or terminated). Overall, of the PMRs that are pending (i.e., have not been initiated, but do not meet the definition for delayed), 78 percent (411/527) were created within the past 3 years.

Table 2 of this document shows that 53 percent (260/527) 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) (21 U.S.C. 355c(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, 253/527) 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 19 percent of the total for NDAs/ANDAs and 17 percent for BLAs) are delayed according to the original schedule milestones (98 percent (141/144) for NDAs/ANDAs; 93 percent (26/28) 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.

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 52 percent (111/215) of the on-schedule NDA/ANDA PMCs and 40 percent (79/200) 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 27 percent for NDAs/ANDAs and 24 percent for BLAs) are delayed according to the original schedule milestones (92 percent (72/78) for NDAs/ANDAs; 97 percent (61/63) for BLAs).

Table 6 of this document provides details about PMRs and PMCs that were concluded in FY2012. The majority of concluded PMRs and PMCs were fulfilled (67 percent of NDA/ANDA PMRs and 63 percent of BLA PMRs; 58 percent of NDA/ANDA PMCs and 85 percent of BLA PMCs).

---

[5] The number of unique NDAs/ANDAs (476) is noticeably different from the corresponding number in the FY2011 Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments (77 FR 13339, March 6, 2012). The FY2011 calculation (198) was based on PMRs/PMCs that were both open at the end of the FY and had received a status update during the year. The FY2012 calculation includes *all* PMRs/PMCs open at the end of FY2012, regardless of when the last status update occurred. Applying FY2011 calculation methods to FY2012 results in 252 unique NDAs/ANDAs with open PMRs/PMCs.

[6] The number of expected annual status reports (432) is different from the total number of unique NDAs/ANDAs with open PMRs/PMCs (476) because not all NDAs/ANDAs had an annual status report due during FY2012. PMRs/PMCs associated with multiple NDAs/ANDAs may submit the annual status report to only one of the applications. In addition, if all of the PMRs/PMCs for an application were established in FY2012, or if all PMRs/PMCs for an application were concluded before the annual status report due date, submission of an annual status report would not be expected.

[7] In the FY2011 FR notice, the percentage of NDA/ANDA annual status reports submitted on time (79 percent) was based on applications that had *both* an open PMR/PMC as of September 30, 2011, *and* had received an annual report during the FY. The corresponding FY2012 calculation is based on applications with an annual status report due date during FY2012, regardless of whether a report was actually received during the FY or whether PMRs/PMCs were closed as of September 30, 2012. Applying the FY2011 calculation method to FY2012 results in 84 percent (166/197) of NDA/ANDA annual status reports submitted on time.

[8] The FY2011 FR notice reported that 100 percent of the annual status reports due, but not submitted on time, were submitted before the close of FY2011. The corresponding percentage is only 49 percent in FY2012. In FY2011, the percentage of annual reports not received on time was based only on reports received within FY2011. The FY2012 calculation considers all reports expected, not just those actually received during FY2012. Applying the FY2011 calculation method to FY2012 results in 100 percent (31/31) of annual status reports due, but not submitted on time, that were submitted before the close of FY2012.

TABLE 1—SUMMARY OF POSTMARKETING REQUIREMENTS AND COMMITMENTS

[Numbers as of September 30, 2012]

| | Number of NDA/ANDA PMRs/PMCs (% of total PMR or % of total PMC) | Number of BLA PMRs/PMCs (% of total PMR or % of total PMC) [1] |
|---|---|---|
| Number of open PMRs | 776 | 167 |
| On-schedule open PMRs (see table 2 of this document). | 632 (81%) | 139 (83%) |
| Off-schedule open PMRs (see table 3 of this document). | 144 (19%) | 28 (17%) |
| Number of open PMCs | 293 | 263 |
| On-schedule open PMCs (see table 4 of this document). | 215 (73%) | 200 (76%) |
| Off-schedule open PMCs (see table 5 of this document). | 78 (27%) | 63 (24%) |

[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, 2012]

| On-Schedule Open PMRs | Number of NDA/ANDA PMRs (% of total PMR) | Number of BLA PMRs (% of total PMR) [1] |
|---|---|---|
| Pending (by type): | | |
| Accelerated approval | 10 | 2 |
| PREA [2] | 236 | 24 |
| Animal efficacy [3] | 2 | 0 |
| FDAAA safety (since March 25, 2008) | 203 | 50 |
| Total | 451 (58%) | 76 (46%) |
| Ongoing: | | |
| Accelerated approval | 11 | 8 |
| PREA [2] | 40 | 6 |
| Animal efficacy [3] | 0 | 0 |
| FDAAA safety (since March 25, 2008) | 68 | 28 |
| Total | 119 (15%) | 42 (25%) |
| Submitted: | | |
| Accelerated approval | 0 | 1 |
| PREA [2] | 20 | 7 |
| Animal efficacy [3] | 0 | 0 |
| FDAAA safety (since March 25, 2008) | 42 | 13 |
| Total | 62 (8%) | 21 (13%) |
| Combined total | 632 (81%) | 139 (84%) |

[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 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 (§ 314.600 for drugs; § 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, 2012]

| Off-schedule open PMRs | Number of NDA/ANDA PMRs (% of total PMR) | Number of BLA PMRs (% of total PMR) [1] |
|---|---|---|
| Delayed: | | |
| Accelerated approval | 5 | 2 |
| PREA | 107 | 14 |
| Animal efficacy | 1 | 0 |
| FDAAA safety (since March 25, 2008) | 28 | 10 |
| Total | 141 (18.2%) | 26 (16%) |
| Terminated | 3 (0.4%) | 2 (1%) |

TABLE 3—SUMMARY OF OFF-SCHEDULE POSTMARKETING REQUIREMENTS—Continued

[Numbers as of September 30, 2012]

| Off-schedule open PMRs | Number of NDA/ANDA PMRs (% of total PMR) | Number of BLA PMRs (% of total PMR) [1] |
|---|---|---|
| Combined total | 144 (19%) | 28 (17%) |

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

TABLE 4—SUMMARY OF ON-SCHEDULE POSTMARKETING COMMITMENTS

[Numbers as of September 30, 2012]

| On-schedule open PMCs | Number of NDA/ANDA PMCs (% of total PMC) | Number of BLA PMCs (% of total PMC) [1] |
|---|---|---|
| Pending | 111 (38%) | 79 (30%) |
| Ongoing | 56 (19%) | 71 (27%) |
| Submitted | 48 (16%) | 50 (19%) |
| Combined total | 215 (73%) | 200 (76%) |

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

TABLE 5—SUMMARY OF OFF-SCHEDULE POSTMARKETING COMMITMENTS

[Numbers as of September 30, 2012]

| Off-schedule open PMCs | Number of NDA/ANDA PMCs (% of total PMC) | Number of BLA PMCs (% of total PMC) [1] |
|---|---|---|
| Delayed | 72 (25%) | 61 (23%) |
| Terminated | 6 (2%) | 2 (0.8%) |
| Combined tota | 78 (27%) | 63 (24%) |

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

TABLE 6—SUMMARY OF CONCLUDED POSTMARKETING REQUIREMENTS AND COMMITMENTS

[October 1, 2011 to October 1, 2012]

| | Number of NDA/ANDA PMRs/PMCs (% of Total) | Number of BLA PMRs/PMCs (% of Total) [1] |
|---|---|---|
| Concluded PMRs: | | |
| Requirement met (fulfilled) | 74 (67%) | 12 (63%) |
| Requirement not met (released and new revised requirement issued). | 6 (6%) | 1 (5%) |
| Requirement no longer feasible or product withdrawn (released). | 30 (27%) | 6 (32%) |
| Total | 110 | 19 |
| Concluded PMCs: | | |
| Commitment met (fulfilled) | 66 (58%) | 34 (85%) |
| Commitment not met (released and new revised requirement/commitment issued). | 0 (0) | 0 (0) |
| Commitment no longer feasible or product withdrawn (released). | 47 (42%) | 6 (15%) |
| Total | 113 | 40 |

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

Dated: February 6, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014–03353 Filed 2–14–14; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Agency Information Collection Activities: Proposed Collection: Public Comment Request

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this Information Collection Request must be received within 60 days of this notice.

**ADDRESSES:** Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information request collection title for reference.

*Information Collection Request Title:* Rural Health Care Services Outreach Supplement Performance Measures.

OMB No. 0915–xxxx—NEW

*Abstract:* The fiscal year (FY) 2013 supplemental funding to the Rural Health Care Services Outreach Program grantees is a one-time supplemental funding under Section 330A(e) of the Public Health Service (PHS) Act (42 U.S.C. 254c(e)) to promote rural health care services outreach by expanding the delivery of health care services to include new and enhanced services in rural areas. The supplemental funding will specifically focus on supporting the current scope of their project, allowing grantees to further enhance outreach and enrollment assistance activities in their communities. This supplemental funding will support the Affordable Care Act's (ACA) outreach and enrollment activities to the Health Insurance Marketplaces. Grantees will be able to raise awareness of affordable insurance options and provide assistance and information to the uninsured about enrolling in available sources of insurance, such as Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and private insurance in the Marketplace through this supplemental funding.

The overarching goal is to increase the number of eligible individuals educated about their coverage options and enrollees to the Health Insurance Marketplaces or other available sources of insurance, such as Medicare, Medicaid, and the Children's Health Insurance Program as a result of this supplemental funding.

*Need and Proposed Use of the Information:* For this program, performance measures were drafted to provide data to the program and to enable HRSA to provide aggregate program data. These measures cover the principal topic areas of interest to the Office of Rural Health Policy, including: (a) Organizational information; (b) outreach and enrollment personnel; (c) outreach and education; (d) enrollment; and (e) additional resources. Several measures will be used for this program.

*Likely Respondents:* The respondents would be recipients of the Rural Health Care Services Outreach supplemental funding award.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

Total Estimated Annualized burden hours:

| Form name | Number of respondents | Number of responses per respondent | Total responses | Average burden per response (in hours) | Total burden hours |
|---|---|---|---|---|---|
| Rural Health Care Services Outreach Supplement Performance Measures .. | 52 | 1 | 52 | 1.5 | 78 |
| Total ..... | 52 | 1 | 52 | 1.5 | 78 |

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Dated: February 10, 2014.

**Jackie Painter,**

*Deputy Director, Division of Policy and Information Coordination.*

[FR Doc. 2014–03442 Filed 2–14–14; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Advisory Commission on Childhood Vaccines; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act