TABLE 1—REQUESTS TO WITHDRAW APPROVAL OF APPLICATIONS—Continued

Application No.	Drug	Applicant
ANDA 076315	Topiramate Tablets, 25 mg, 100 mg, and 200 mg	Barr Laboratories, Inc., an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, 400 Chestnut Ridge Rd., Woodcliff Lake, NJ 07677.
ANDA 076372	Brimonidine Tartrate Ophthalmic Solution, 0.2%	Teva Parenteral Medicines, Inc.
ANDA 076398	Tamoxifen Citrate Tablets USP, 10 mg and 20 mg	Aegis Pharmaceuticals PLC, c/o GlobePharm Inc., 313 Pine St., Suite 204, Deerfield, IL 60015.
ANDA 076424	Fluconazole Tablets, 50 mg, 100 mg, 150 mg, and 200 mg ..	Pliva Inc., c/o Barr Laboratories Inc., an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, U.S. Agent, 400 Chestnut Ridge Rd., Woodcliff Lake, NJ 07677.
ANDA 076448	Topiramate Capsules, 15 mg and 25 mg	Barr Laboratories, Inc.
ANDA 076529	Loratadine Syrup (loratadine oral solution USP), 1 mg/mL	Ranbaxy Laboratories Limited, c/o Ranbaxy Inc., U.S., 600 College Rd. East, Princeton, NJ 08540.
ANDA 076540	Sertraline HCl Tablets, 25 mg, 50 mg, and 100 mg	Mylan Pharmaceuticals, Inc.
ANDA 076612	Benazepril HCl and Hydrochlorothiazide Tablets, 5 mg/6.25 mg, 10 mg/12.5 mg, 20 mg/12.5 mg, and 20 mg/25 mg.	Do.
ANDA 076640	Metoprolol Succinate Extended-Release Tablets, 100 mg and 200 mg.	Nesher Pharmaceuticals (USA) LLC.
ANDA 076865	Fluticasone Proprionate Cream, 0.05%	Do.
ANDA 076982	Prednisolone Sodium Phosphate Oral Solution USP, 5 mg/5 mL.	Do.
ANDA 076992	Ciprofloxacin Injection USP, 10 mg/mL	Bedford Laboratories.
ANDA 076993	Ciprofloxacin Injection USP, 10 mg/mL	Do.
ANDA 077074	Lorazepam Injection USP (Preservative-Free), 2 mg/mL and 4 mg/mL.	Do.
ANDA 077076	Lorazepam Injection USP, 2 mg/mL and 4 mg/mL, 10 mL per vial.	Do.
ANDA 077080	Amlodipine Besylate Tablets, 2.5 mg, 5 mg, and 10 mg	Synthon Pharmaceuticals, Inc., 9000 Development Dr., P.O. Box 110487, Research Triangle Park, NC 27709.
ANDA 077085	Leflunomide Tablets, 10 mg and 20 mg	Sandoz Inc.
ANDA 077311	Hydromorphone HCl Tablets USP, 2 mg, 4 mg, and 8 mg	Nesher Pharmaceuticals (USA) LLC.
ANDA 085917	Acetaminophen and Codeine Phosphate Tablets, 30 mg	Sandoz Inc.
ANDA 087423	Acetaminophen and Codeine Phosphate Tablets, 300 mg/60 mg.	Do.
ANDA 087433	Acetaminophen and Codeine Phosphate Tablets, 300 mg/15 mg.	Do.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner, approval of the applications listed in table 1 in this document, and all amendments and supplements thereto, is hereby withdrawn, effective May 22, 2014. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the FD&C Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in table 1 that are in inventory on the date that this notice becomes effective (see the DATES section) may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: April 17, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–09124 Filed 4–21–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than May 22, 2014.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Children's Hospitals Graduate Medical Education Payment Program.

OMB No.: 0915–0247 Revision.

Abstract: The Children's Hospitals Graduate Medical Education (CHGME) Payment Program was enacted by Public Law 106–129 to provide federal support for graduate medical education (GME) to freestanding children's hospitals. This legislation attempts to provide support for GME comparable to the level of Medicare GME support received by other, non-children's hospitals. The legislation requires that eligible children's hospitals receive payments for both direct and indirect medical

education expenses. Payments for direct expenses offset the expenses associated with operating approved graduate medical residency training programs, and payments for indirect expenses compensate hospitals for expenses associated with the treatment of more severely ill patients and the additional costs relating to teaching residents in such programs. The Centers for Medicare and Medicaid Services (CMS) issued a final rule in the **Federal Register** regarding Sections 5503, 5504, 5505, and 5506 of the Affordable Care Act of 2010, Public Law 111–148, on Wednesday, November 24, 2010. This final rule included policy changes on counting resident time in non-provider settings, counting resident time for didactic training and the redistribution of resident caps, which required modification of the data collection forms within the CHGME Payment Program application. The necessary modifications were made and received OMB clearance on June 30, 2012.

On September 30, 2013, CMS published revised cost report forms on their Web site; specifically form CMS 2552–10, Worksheet E–4, requiring additional modifications of the data collection forms in the CHGME Payment Program application. The CHGME Payment Program application forms have been adjusted to accommodate the most recent CMS policy changes. These changes require OMB approval.

Need and Proposed Use of the Information: Data are collected on the number of full-time equivalent (FTE) residents in applicant children's hospitals' training programs to determine the amount of direct and indirect medical education payments to be distributed to participating children's hospitals. Indirect medical education payments will also be derived from a formula that requires the reporting of discharges, beds, and case mix index information from participating children's hospitals.

Hospitals will also be requested to submit data on the number of FTE residents trained during the federal fiscal year to participate in the reconciliation payment process. Auditors will be requested to submit data on the number of full-time equivalent residents trained by the hospitals in an FTE resident assessment summary. An assessment of the hospital data ensures that appropriate CMS regulations and CHGME program guidelines are followed in determining which residents are eligible to be claimed for funding. The audit results impact final payments made by the CHGME Payment Program to all eligible hospitals.

Likely Respondents: Hospitals applying for and receiving CHGME funds and fiscal intermediaries auditing data submitted by the hospitals receiving CHGME funds.

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
Application Cover Letter (Initial)	60	1	60	0.33	19.8
Application Cover Letter (Reconciliation)	60	1	60	0.33	19.8
HRSA 99 (Initial)	60	1	60	0.33	19.8
HRSA 99 (Reconciliation)	60	1	60	0.33	19.8
HRSA 99–1 (Initial)	60	1	60	26.50	1,590.0
HRSA 99–1 (Reconciliation)	60	1	60	6.50	390.0
HRSA 99–1 (Supplemental) (FTE Resident Assessment)	30	1	30	3.67	110.1
HRSA 99–2 (Initial)	60	1	60	11.33	679.8
HRSA 99–2 (Reconciliation)	60	1	60	3.67	220.2
HRSA 99–4 (Reconciliation)	60	1	60	12.50	750.0
HRSA 99–5 (Initial)	60	1	60	0.33	19.8
HRSA 99–5 (Reconciliation)	60	1	60	0.33	19.8
CFO Form Letter (Initial)	60	1	60	0.33	19.8
CFO Form Letter (Reconciliation)	60	1	60	0.33	19.8
FTE Resident Assessment Cover Letter (FTE Resident Assessment)	30	1	30	0.33	9.9
Conversation Record (FTE Resident Assessment)	30	1	30	3.67	110.1
Exhibit C (FTE Resident Assessment)	30	1	30	3.67	110.1
Exhibit F (FTE Resident Assessment)	30	1	30	3.67	110.1
Exhibit N (FTE Resident Assessment)	30	1	30	3.67	110.1
Exhibit O(1) (FTE Resident Assessment)	30	1	30	3.67	110.1
Exhibit O(2) (FTE Resident Assessment)	30	1	30	26.50	795.0
Exhibit P (FTE Resident Assessment)	30	1	30	3.67	110.1
Exhibit P(2) (FTE Resident Assessment)	30	1	30	3.67	110.1
Exhibit S (FTE Resident Assessment)	30	1	30	3.67	110.1
Exhibit T (FTE Resident Assessment)	30	1	30	3.67	110.1
Exhibit T(1) (FTE Resident Assessment)	30	1	30	3.67	110.1
Exhibit 1 (FTE Resident Assessment)	30	1	30	0.33	9.9
Exhibit 2 (Initial, Reconciliation and FTE Resident Assessment)	90	1	90	0.33	29.7
Exhibit 3 (Initial, Reconciliation and FTE Resident Assessment)	90	1	90	0.33	29.7

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS—Continued

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Exhibit 4 (Initial, Reconciliation and FTE Resident Assessment)	90	1	90	0.33	29.7
Total	90		90		5,962.8

Dated: April 14, 2014.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2014–09186 Filed 4–21–14; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than May 22, 2014.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Healthy Start Evaluation and Quality Assurance OMB No. 0915–0338—Revision

Abstract: The National Healthy Start Program, funded through the Health Resources and Services Administration's (HRSA's) Maternal and Child Health Bureau (MCHB), has the goal of reducing disparities in infant mortality and adverse perinatal outcomes. The program began as a demonstration project with 15 grantees in 1991 and has expanded over the past 2 decades to 105 grantees serving 196 communities across 39 states. Healthy Start grantees operate in communities with rates of infant mortality at least 1.5 times the U.S. national average and high rates for other adverse perinatal outcomes. These communities are geographically, racially, ethnically, and linguistically diverse low-income areas. Healthy Start covers services during the perinatal period (before, during, after pregnancy) and follows the woman and infant through 2 years after the end of the pregnancy. The next round of funding represents a transformation of the program framework from nine service and systems core components to five approaches. The five approaches are as follows: (1) Improving women's health; (2) promoting quality services; (3) strengthening family resilience; (4) achieving collective impact; and (5) increasing accountability through quality assurance, performance monitoring, and evaluation.

MCHB seeks to implement a uniform set of data elements for monitoring and conduct a mixed-methods evaluation to assess the effectiveness of the program on individual, organizational, and community-level outcomes. Data collection instruments will include a Preconception, Pregnancy, and Parenting Information Form; National Healthy Start Program Survey; Community Action Network Survey; Healthy Start Site Visit Protocol; and Healthy Start Participant Focus Group Protocol.

Need and Proposed Use of the Information: The purpose of the data collection instruments will be to obtain consistent information across all grantees about Healthy Start and its outcomes for purposes of monitoring, and in-depth information for 15 Healthy Start communities and 15 comparison communities to support a rigorous evaluation design. The data will be used to: (1) Conduct ongoing performance monitoring of the program; (2) provide credible and rigorous evidence of program effect on outcomes; (3) assess the relative contribution of the five program approaches to individual and community-level outcomes; (4) meet program needs for accountability, programmatic decision-making, and ongoing quality assurance; and (5) strengthen the evidence-base, and identify best and promising practices for the program to support sustainability, replication, and dissemination of the program.

Likely Respondents: Respondents include pregnant women and women of reproductive age who are served by the Healthy Start program (monitoring) and sampled postpartum women from 15 unfunded organizations in comparison communities (evaluation) for the Preconception, Pregnancy, and Parenting Information Form; project directors and staff for the National Healthy Start Program Survey; representatives from partner organizations for the Community Action Network Survey; program staff, providers, and partners for the Healthy Start Site Visit Protocol; and program participants for the Healthy Start Participant Focus Group Protocol.

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 ICR are summarized in the table below.