opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 040524	Promethazine Hydrochloride (HCl) Injection USP, 25 milligrams (mg)/milliliter (mL) and 50 mg/mL.	Bedford Laboratories, 300 Northfield Rd., Bedford, OH 44146.
ANDA 070857	Trazodone HCl Tablets USP, 50 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 070987	Diazepam Tablets USP, 2 mg	Halsey Drug Co., Inc., 1827 Pacific St., Brooklyn, NY 11233.
ANDA 070996	Diazepam Tablets USP, 5 mg	Do.
ANDA 071717	Flurazepam HCl Capsules USP, 15 mg and 30 mg	Aurolife Pharma, LLC, 279 Princeton Hightstown Rd., East Windsor, NJ 08520.
ANDA 071751	Methyldopa Tablets USP, 125 mg	Halsey Drug Co., Inc.
ANDA 071752	Methyldopa Tablets USP, 250 mg	Do.
ANDA 077190	Milrinone Lactate Injection, EQ 1 mg base/mL	Gland Pharma, Ltd., c/o INC Research, LLC, 4800 Falls of Neuse Rd., Suite 600, Raleigh, NC 27609.
ANDA 077703	Pamidronate Disodium for Injection USP, 30 mg/vial and 90 mg/vial.	Sun Pharma Global FZE, c/o Sun Pharmaceutical Industries, Inc., 270 Prospect Plains Rd., Cranbury, NJ 08512.
ANDA 080300	Prednisone Tablets USP, 5 mg	Halsey Drug Co., Inc.
ANDA 080961	Chlorpheniramine Maleate Tablets USP, 4 mg	Aurolife Pharma, LLC.
ANDA 083453	Niacin Tablets USP, 500 mg	Halsey Drug Co., Inc.
ANDA 083629	Kloromin (chlorpheniramine maleate) Tablets USP, 4 mg.	Do.
ANDA 083930	Dextroamphetamine Sulfate Tablets USP, 10 mg	Do.
ANDA 084676	Secobarbital Sodium Capsules USP, 100 mg	Do.
ANDA 085088	Hydralazine HCl Tablets USP, 50 mg	Upsher-Smith Laboratories, LLC, 6701 Evenstad Dr., Maple Grove, MN 55369.
ANDA 085219	Hydrochlorothiazide Tablets, 50 mg	Aurolife Pharma, LLC.
ANDA 085923	Amitriptyline HCl Tablets USP, 10 mg	Halsey Drug Co., Inc.
ANDA 087279	Butalbital, Aspirin, and Caffeine Tablets	Sandoz, Inc., 227–15 North Conduit Ave., Laurelton, NY 11413.
ANDA 088116	Myfed (pseudoephedrine HCl and triprolidine HCl) Syrup, 30 mg/5 mL and 1.25 mg/5 mL.	USL Pharma, LLC, 301 South Cherokee St., Denver, CO 80223.
ANDA 088725	Chlorpropamide Tablets USP, 100 mg	Aurolife Pharma, LLC.
ANDA 089130	Hydralazine HCl Tablets USP, 25 mg	Halsey Drug Co., Inc.
ANDA 089178	Hydralazine HCl Tablets USP, 100 mg	Do.
ANDA 201484	Levofloxacin Tablets, 250 mg, 500 mg, and 750 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of June 24, 2019. Approval of each entire application is withdrawn, including any strengths or products inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on June 24, 2019, 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: May 20, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–10809 Filed 5–22–19; 8:45 am]

BILLING CODE 4164–01–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; Information Collection Request Title: Maternal and Child Health Bureau Performance Measures for Discretionary Grant Information System (DGIS), OMB No. 0915–0298—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, 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 June 24, 2019.

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 Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Maternal and Child Health Bureau Performance Measures for Discretionary Grant Information System (DGIS), OMB No. 0915–0298—Revision.

Abstract: This Information Collection Request is for continued approval of performance measures for HRSA's Maternal and Child Health Bureau (MCHB) discretionary grants, specifically, the continued use of reporting requirements for grant programs administered by MCHB in accordance with the ''Government Performance and Results Act of 1993'' (Pub. L. 103–62). This Act requires the preparation of an annual performance plan covering each program activity set forth in the agency's budget, which includes establishment of measurable goals that may be reported in an annual financial statement to support the linkage of funding decisions with performance. Performance measures for MCHB discretionary grants were initially approved in 2003, and the latest approval was obtained in 2016 for significant revisions. OMB approval is currently being sought to continue the use of performance measures with minor revisions. Most of these measures are specific to certain types of programs and are not required of all grantees. The measures are categorized by domains (Adolescent Health, Capacity Building, Child Health, Children with Special Health Care Needs, Lifecourse/Crosscutting, Maternal/Women Health, and Perinatal/Infant Health). In addition, there are some program-specific measures. Grant programs are assigned domains based on their activities. HRSA is proposing to make changes to the DGIS to more closely align data collection forms with current program activities. These revisions will facilitate more accurate reporting of descriptive information related to Long-term Trainees in Maternal and Child Health, as well as activities related to Technical Assistance for programs. Proposed changes include the following:

- Trainee Information (Long-term Trainees Only) form:
  - Changes will incorporate options and titles that were omitted from the final submission of the previous OMB package, providing clarification for the reporting of specific descriptive information about Long-term Trainees on the form.
  - Changes will list the following options for ''Type'': ''Non-Degree Seeking,'' ''Undergraduate,'' ''Masters,'' ''Doctoral,'' Post-doctoral,'' ''Other.''
  - Changes will list the title ''Student Status'' next to the options for ''Part-time student'' and ''Full-time student.''
- Technical Assistance/Collaboration form:
  - Add a field asking for the ''Total number of TA recipients.'' This change will allow for better alignment with this data that was previously collected by program, but omitted due to a DGIS paper form error.
  - Add an ''Other'' category to List B under ''Topic of Technical Assistance/Collaboration.'' This change would facilitate more accurate data reporting by providing programs an additional category to choose from if their current Technical Assistance activities do not closely align with the existing categories in List B.

A 60-day **Federal Register** Notice was published in the **Federal Register** on November 13, 2018 Vol. 83, No. 219, pp. 56353–54). No public comments were received.

Need and Proposed Use of the Information: The performance data collected through the DGIS serves several purposes, including grantee monitoring, program planning, performance reporting, and the ability to demonstrate alignment between MCHB discretionary programs and the Title V MCH Services Block Grant program. This revision will facilitate more accurate reporting of descriptive information related to Long-term Trainees in Maternal and Child Health, as well as activities related to Technical Assistance for programs.

Likely Respondents: The grantees for Maternal and Child Health Bureau Discretionary Grant Programs.

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.

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
Grant Report	700	1	700	36	25,200
Total	700		700		25,200

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2019–10807 Filed 5–22–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Nominations to the Advisory Council on Alzheimer's Research, Care, and Services

AGENCY: Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Secretary of HHS established the Advisory Council to provide advice and consultation to the Secretary on how to prevent or reduce the burden of Alzheimer's disease and related dementias on people with the disease and their caregivers. The Secretary signed the charter establishing the Advisory Council on May 23, 2011. *HHS is soliciting nominations for five (5) new non-Federal members of the Advisory Council to replace the five members whose terms will end September 30, 2019.* Nominations should include the nominee's contact information (current mailing address, email address, and telephone number) and current curriculum vitae or resume.

DATES: Submit nominations by email or USPS mail before COB on June 28, 2019.

ADDRESSES: Nominations should be sent by email to Helen Lamont at *helen.lamont@hhs.gov;* or sent by USPS mail to: Helen Lamont, Office of the Assistant Secretary for Planning and Evaluation, Room 424E, Humphrey Building, 200