410–786–8466 or *Candace.Carter@cms.hhs.gov*).

4. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* End Stage Renal Disease (ESRD) Annual Home Dialysis within Nursing Home Survey Form; *Use:* The End Stage Renal Disease (ESRD) Network program is responsible to collect, validate, and analyze data as well as to evaluate the process by which facilities determine the appropriateness of patients for a treatment modality. Additional responsibilities of the ESRD Network program include encouraging participation in the placement of patients in a self-care setting, such as home hemodialysis or peritoneal dialysis, as described in Sec. 1881. [42 U.S.C. 1395rr] (c)(1)(A)(i)(2) of the Social Security Act. On September 21, 2018, CMS clarified guidance that residents in a nursing home facility can receive dialysis either administered and/or supervised by personnel who meet the criteria for training, and competency verification at 42 CFR 494.100(a) and (b) for providing dialysis. The provision of dialysis within a nursing home requires that the dialysis facility have an agreement with the nursing home. This guidance was reinforced and updated on March 22, 2023, in a memo to the State Survey Agency Directors titled, ''Guidance and Survey Process for Reviewing Home Dialysis Services in a Nursing Home REVISED''. Since the provision of dialysis within nursing homes is relatively new, CMS designed the CMS–10842 form to capture home modality information from dialysis facilities that provide dialysis within the nursing home in alignment with the Centers for Disease Control and Prevention (CDC).

The care provided to residents of a nursing home is of particular interest because of the fragile health state of the patient and the susceptibility to infection. Each facility certification/survey record represents one provider. CMS–10842 collects information on dialysis facilities providing home dialysis services within the nursing home related to the number of patients, setting of dialysis services provided, who is providing dialysis services, who is providing dressing changes to dialysis access, staff education and use of CDC Core Interventions used. The aggregate patient information is collected from each Medicare-approved home dialysis provider to identify the specialized needs of the ESRD community where home dialysis is provided in Long Term Care facilities. *Form Number:* CMS–10842 (OMB control number: 0938–NEW); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents:* 7,726; *Total Annual Responses:* 7,726; *Total Annual Hours:* 5,795. (For policy questions regarding this collection contact Christina Goatee at 410–786–6689).

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–07202 Filed 4–4–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget Review; Proposed Information Collection Activity; Tribal Early Childhood Facilities Combined Application Guide (New Collection)

AGENCY: Office of Early Childhood Development, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Early Childhood Development (ECD), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is requesting Office of Management and Budget (OMB) approval of the Tribal Early Childhood Facilities Combined Application Guide for joint applications for construction and major renovation projects using both Head Start and Child Care and Development Fund (CCDF) resources.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Funding for facilities under the CCDF is authorized by Section 658O(c)(6) of the Child Care and Development Block Grant (CCDBG) Act, 42 U.S.C. 9858(c)(6), and is managed by the Office of Child Care (OCC). Funding for Head Start facilities projects is authorized by 45 CFR part 1303 (Subpart E) Head Start Program Performance Standards and is managed by the Office of Head Start (OHS). The guide streamlines the process for Tribal CCDF Lead Agencies and American Indian and Alaska Native (AI/AN) Head Start programs submitting collaborative, joint applications to use federal CCDF and Head Start funds for facilities projects where funds can be used for reasonable costs and fees related to planning for a facilities project and to support the application development in tribal communities. Both funds aim to construct or improve early childhood facilities, often serving the same children, but application submission and review processes are currently unique to each respective funding stream. The proposed information collection will provide instructions to Tribal CCDF Lead Agencies and AI/AN Head Start programs on submitting joint plans for how proposed facilities projects will enable the programs to better serve current AI/AN families or increase enrollment currently limited by inadequate facilities. The guide will provide critical information and resources, so recipients understand the requirements of each program and develop plans that reflect the needs of their communities. Reducing and streamlining administrative burdens for tribal constituents follows policy priorities laid out in the 2022 HHS Equity Action Plan and is in alignment with Executive Order 14095—Executive Order on Increasing Access to High-Quality Care and Supporting Caregivers.

Respondents: AI/AN Head Start Facilities and Tribal CCDF Lead Agencies (information collection does not include direct interaction with individuals or families that receive the services).

Annual Burden Estimates: We estimate at most 10 applications per year and have estimated burden based on this maximum number.

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Tribal Early Childhood Facilities Application Guide	10	1	100	1,000

Authority: 42 U.S.C. 9858(c)(6); 45 CFR part 1303 Subpart E.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–07292 Filed 4–4–24; 8:45 am]

BILLING CODE 4184–40–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–P–0105]

Determination That GLUCOTROL (Glipizide) Tablets, 5 Milligrams and 10 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that GLUCOTROL (glipizide) tablets, 5 milligrams (mg) and 10 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to these products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Swati Rawani, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6221, Silver Spring, MD 20993–0002, 240–402–9917, *Swati.Rawani@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

GLUCOTROL (glipizide) tablets, 5 mg and 10 mg, are the subject of NDA 017783, held by Pfizer Inc., and initially approved on May 8, 1984. GLUCOTROL is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

In a letter dated June 30, 2022, Pfizer Inc., notified FDA that GLUCOTROL (glipizide) tablets, 5 mg and 10 mg, were being discontinued, and FDA moved these drug products to the ''Discontinued Drug Product List'' section of the Orange Book.

Graviti Pharmaceuticals Private Limited submitted a citizen petition dated January 3, 2024, Docket No. FDA–2024–P–0105, under 21 CFR 10.30, requesting that the Agency determine whether GLUCOTROL (glipizide) tablets, 5 mg and 10 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that GLUCOTROL (glipizide) tablets, 5 mg and 10 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that GLUCOTROL (glipizide) tablets, 5 mg and 10 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of GLUCOTROL (glipizide) tablets, 5 mg and 10 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that these drug products were not withdrawn from sale for reasons of safety or effectiveness.[1]

Accordingly, the Agency will continue to list GLUCOTROL (glipizide) tablets, 5 mg and 10 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to these drug products. Additional ANDAs for these drug products may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: April 2, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–07268 Filed 4–4–24; 8:45 am]

BILLING CODE 4164–01–P

[1] FDA previously determined that GLUCOTROL (glipizide) tablets, 2.5 mg, were not withdrawn from sale for reasons of safety or effectiveness (87 FR 28015, May 10, 2022).