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.

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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Determination That GLUCOTROL (Glipizide) Tablets, 5 Milligrams and 10 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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Administration (FDA or Agency) has determined that GLUCOTROL (glipizide) tablets, 5 milligrams (mg) and 10 mg, were not withdrawn from sale for reasons of safety or effectiveness.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.

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[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).