GLUCOTROL (glipizide) tablets, 2.5 mg, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Hyman, Phelps & McNamara, P.C., submitted a citizen petition dated August 24, 2021 (Docket No. FDA–2021–P–0939), under 21 CFR 10.30, requesting that the Agency determine whether GLUCOTROL (glipizide) tablets, 2.5 mg, were withdrawn from sale for reasons of safety or effectiveness.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we have at this time, FDA has determined under § 314.161 that GLUCOTROL (glipizide) tablets, 2.5 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that GLUCOTROL (glipizide) tablets, 2.5 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of GLUCOTROL (glipizide) tablets, 2.5 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list GLUCOTROL (glipizide) tablets, 2.5 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. ANDAs that refer to GLUCOTROL (glipizide) tablets, 2.5 mg, may 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 this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: May 4, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09944 Filed 5–9–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2014–N–1721; FDA–2005–N–0101; FDA–2021–N–0386; FDA–2012–N–0294; and FDA–2018–N–3404]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections approved recently by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Investigational New Drug Regulations	0910–0014	3/31/2025
Prescription Drug User Fee Program	0910–0297	3/31/2025
Medical Device Reporting	0910–0437	3/31/2025
Food Additives; Food Contact Substances Notification System	0910–0495	3/31/2025
Generic Drug User Fee Program	0910–0727	3/31/2025

Dated: May 4, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–10017 Filed 5–9–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0168]

Benefit-Risk Considerations for Product Quality Assessments; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Benefit-Risk Considerations for Product Quality Assessments.'' This guidance describes the benefit-risk principles applied by FDA when conducting product quality-related assessments of chemistry, manufacturing, and controls (CMC) information submitted for FDA assessment as part of original new drug applications (NDAs), original biologics license applications (BLAs), or supplements to such applications, in addition to other information (*e.g.,* inspectional findings) available to FDA during its assessment. This guidance discusses how FDA assesses risks, sources of uncertainty, and possible mitigation strategies for a product quality-related issue and how those considerations inform FDA's understanding of the potential effect on a product. This guidance also discusses how unresolved product quality issues may be addressed in the context of regulatory decision making. The guidance notes that product quality assessments are also done for abbreviated new drug applications (ANDAs), and it discusses how, in certain rare circumstances, unresolved product quality issues may be addressed when there is an urgent clinical need for