DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–6382]

SpecGx LLC; Withdrawal of Approval of Abbreviated New Drug Application for Methylphenidate Hydrochloride Extended-Release Tablets, 27 Milligrams, 36 Milligrams, and 54 Milligrams

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of abbreviated new drug application (ANDA) 202608 for Methylphenidate Hydrochloride (HCl) Extended-Release (ER) tablets, 27 milligrams (mg), 36 mg, and 54 mg, held by SpecGx LLC (SpecGx), 385 Marshall Ave., Webster Groves, MO 63119. SpecGx requested withdrawal of approval of this application and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of June 18, 2026.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: On December 28, 2012, FDA approved ANDA 202608 for Methylphenidate HCl ER tablets, 27 mg, 36 mg, and 54 mg. The reference listed drug (RLD) is CONCERTA (methylphenidate HCl) ER tablets, which are approved under new drug application (NDA) 021121 in strengths of 18 mg, 27 mg, 36 mg, and 54 mg.

At the time of approval, FDA determined that ANDA 202608 included data sufficient to demonstrate the bioequivalence of SpecGx's [1] Methylphenidate HCl ER tablets to CONCERTA. The bioequivalence testing and data submitted in the ANDA conformed to recommendations provided in a draft guidance for industry on ''Methylphenidate hydrochloride.'' The draft guidance was issued on September 14, 2012 (77 FR 56851) and provided information and recommendations for establishing bioequivalence to CONCERTA that reflected CDER's understanding, at that time, of how to evaluate the pharmacokinetic properties of CONCERTA to support a demonstration of bioequivalence.

Subsequently, FDA received adverse event reports that described insufficient therapeutic effect of SpecGx's Methylphenidate HCl ER tablets, particularly later in the day. After reevaluating the question of what evidence is needed to demonstrate bioequivalence to CONCERTA, CDER concluded that, to ensure therapeutic effect throughout the 12-hour therapeutic time course for which CONCERTA is labeled, an absence of a significant difference in drug exposure between a proposed generic product and CONCERTA must be shown during the entire therapeutic time course, including the latter part of the 12-hour period after drug administration. On November 6, 2014 (79 FR 65978), CDER issued a revised draft guidance for industry on ''Bioequivalence Recommendations for CONCERTA (Methylphenidate Hydrochloride) Extended-Release Tablets,'' with recommendations for establishing bioequivalence to CONCERTA that reflected CDER's refined understanding of the relationship between the pharmacokinetic profile of CONCERTA and its therapeutic effect.

After continuing to evaluate data and information related to the bioequivalence of SpecGx's Methylphenidate HCl ER tablets to CONCERTA, including the bioequivalence data originally submitted in ANDA 202608 and data from a March 2015 CDER-sponsored study evaluating the bioequivalence of SpecGx's 27 mg product to CONCERTA, CDER determined that SpecGx's Methylphenidate HCl ER tablets had not been shown to be bioequivalent to CONCERTA. Therefore, CDER proposed to withdraw approval of ANDA 202608 under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)) and § 314.150(a) (21 CFR 314.150(a)).

On October 18, 2016, in Docket No. FDA–2016–N–3118, CDER published a notice of opportunity for hearing (NOOH) on its proposal to withdraw approval of ANDA 202608 for Methylphenidate HCl ER tablets (81 FR 71737). SpecGx submitted a timely request for hearing on November 10, 2016. In February 2026, CDER recommended to FDA's Office of the Commissioner that SpecGx be granted a hearing and submitted to the docket, among other things, CDER's analysis of SpecGx's hearing request. On March 25, 2026, SpecGx and CDER submitted a joint request to pause the proceedings to withdraw approval of ANDA 202608 that are the subject of Docket No. FDA–2016–N–3118. FDA's Office of the Commissioner granted this joint request on April 20, 2026.

FDA is now withdrawing approval of ANDA 202608 under § 314.150(d). For the reasons described in the NOOH and CDER's analysis of SpecGx's hearing request in Docket No. FDA–2016–N–3118, FDA believes the potential problem with respect to the bioequivalence of SpecGx's Methylphenidate HCl ER tablets to CONCERTA is sufficiently serious that the drug should be removed from the market.

On March 12, 2026, at FDA's request, SpecGx submitted a request that FDA withdraw approval of ANDA 202608 for Methylphenidate HCl ER tablets under § 314.150(d) and waived its opportunity for a hearing under § 314.150(a). SpecGx agreed to request withdrawal of approval of ANDA 202608 under § 314.150(d) based on the Agency's position that sufficient bioequivalence data is lacking.

For the reasons discussed above, and in accordance with the applicant's request, approval of ANDA 202608 for Methylphenidate HCl ER tablets, 27 mg, 36 mg, and 54 mg, and all amendments and supplements thereto, is withdrawn under § 314.150(d). Distribution of Methylphenidate HCl ER tablets, 27 mg, 36 mg, and 54 mg, into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d))).

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–12236 Filed 6–17–26; 8:45 am]

BILLING CODE 4164–01–P

[1] The current application holder for ANDA 202608 is SpecGx LLC, a subsidiary of Mallinckrodt Pharmaceuticals. Mallinckrodt Pharmaceuticals was the previous application holder. In documents previously posted to Docket No. FDA–2016–N–3118, SpecGx LLC and Mallinckrodt Pharmaceuticals are referred to collectively as ''Mallinckrodt.'' In this document, we refer to the application holder of ANDA 202608 as SpecGx throughout.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–0008]

Advisory Committee; Science Board to the Food and Drug Administration; Renewal

AGENCY: Food and Drug Administration, HHS.