## 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**DATES:** Approval is withdrawn as of June 18, 2026.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 The bioequivalence testing and data submitted in the ANDA conformed to recommendations provided in a draft guidance for industry on ''Methylphenidate hydrochloride.'' The draft guidance was issued on September 14, 2012 (77 FR 56851) and provided information and recommendations for establishing bioequivalence to CONCERTA that reflected CDER's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.

**ACTION:** Notice; renewal of Federal advisory committee.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the renewal of the Science Board to the Food and Drug Administration by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Science Board to the Food and Drug Administration for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the June 26, 2028, expiration date.

**DATES:** The Science Board to the Food and Drug Administration will expire on June 26, 2026, unless the Commissioner formally determines that renewal is in the public interest.

**FOR FURTHER INFORMATION CONTACT:** Advisory Committee Oversight and Management Staff, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3215, Silver Spring, MD 20993–0002, (301) 796–8220, *ACOMSSubmissions@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Science Board to the Food and Drug Administration (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates data concerning specific complex scientific and technical issues important to FDA and its mission, including emerging issues within the scientific community, and makes appropriate recommendations to the Commissioner.

The Committee shall consist of a core of at least 15 voting members including the Chair. Subject to legal and regulatory requirements, members and the Chair are selected by and serve at the discretion of the Commissioner or designee. Each member, including the Chair, will be selected from among authorities knowledgeable in the fields of food science (safety and nutrition); clinical research; veterinary medicine; pharmacology; toxicology; biostatistics; medical devices; public health and epidemiology; product manufacturing and quality; and other scientific areas relevant to FDA regulated products such as systems biology, informatics, nanotechnology, and combination products.

Members may be invited to serve for terms of up to four years, or for less time in the discretion of the Commissioner or designee. Non-Federal members of this committee will serve as Special Government Employees or representatives. Federal members will serve as Regular Government Employees or ExOfficios. The core of voting members may include 1 technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees to serve temporarily as voting members and to designate Special Government Employees to serve temporarily as voting members when: (1) expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members), or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking.

A quorum for the Committee is a majority of the current voting members present at the time, provided that FDA may specify a quorum that is less than a majority of the current voting members because of the size of the Committee and the variety in the types of issues that it will consider, or other reason determined appropriate in accordance with legal and regulatory requirements. 21 CFR 14.22(d).

If functioning as a medical device panel, an additional non-voting representative member of consumer interests and a non-voting representative member of industry interests will be included in addition to the voting members.

Members appointed to an advisory committee serve for the duration of the committee, or until their terms expire, they resign, or they are removed from membership by the Commissioner or designee. Committee members' terms may be ended prior to their date of expiration, for reasons determined to be good cause. Good cause includes excessive absenteeism from committee meetings, a demonstrated bias that interferes with the ability to render objective advice, failure to abide by established procedures, or violation of other applicable rules and regulations.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/advisory-committees/science-board-food-and-drug-administration/charter-science-board-food-and-drug-administration* or by contacting the Advisory Committee Oversight and Management Staff (see **FOR FURTHER INFORMATION CONTACT**). Because the committee's name and description of duties remain unchanged, 21 CFR 14.100 will not be amended.

*Renewal Requirements and Justification:* The Commissioner has determined that renewal of the Science Board to the Food and Drug Administration is in the public interest. This determination is based on the Committee's essential role in providing independent expert advice concerning specific complex scientific and technical issues important to FDA and its mission, including emerging issues within the scientific community, the continued need for specialized expertise in this area, and the Committee's demonstrated value in supporting FDA's regulatory mission. The following information supports this determination in accordance with applicable legal and regulatory requirements.

*Public Interest Determination:* Pursuant to 41 CFR 102–3.60(a), to establish, renew, reestablish, or merge a discretionary (agency discretion) advisory committee, an agency must first consult with the General Services Administration's Committee Management Secretariat (the Secretariat) and, as part of the consultation, provide a written public interest determination approved by the head of the agency to the Secretariat with a copy to the Office of Management and Budget. In addition, pursuant to 41 CFR 102–3.35, an agency shall follow the same consultation process and document in writing the same determination of need before creating a subcommittee under a discretionary committee that is not made up entirely of members of a parent advisory committee. Information on the following factors for the committee is provided to the Secretariat to demonstrate that renewing the committee is in the public interest:

1. *Annual budget:* The overall annual budget for this committee is $97,121.

a. *Federal personnel on a full-time equivalent (FTE) basis:* The estimated person years of Federal staff support required is 0.20 at an estimated annual cost of $51,087.

b. *Other Federal internal costs:* The anticipated total value in USD of other internal costs, such as cost associated

with IT and supplies for meetings, is $16,822

c. *Proposed payments to members:* The estimated annual payment to members is $11,170.

d. *Proposed number of members:* The anticipated number of members is 15.

e. *Reimbursable costs:* The estimated annual reimbursable costs, including travel and related expenses for members is $10,760

2. *If applicable, the total dollar value of grants expected to be recommended during the fiscal year:* N/A.

3. *Criteria for selecting members to ensure the committee has the necessary expertise and fairly balanced membership:*

*Ensuring Necessary Expertise:*

Members must have background, education, and experience commensurate with the committee's function of advising FDA on specific complex scientific and technical issues important to FDA and its mission, including emerging issues within the scientific community. Additionally, the Committee will provide advice that supports the Agency in keeping pace with technical and scientific developments, including regulatory science; and input into the Agency's research agenda; and on upgrading its scientific and research facilities and training opportunities. Members will be selected from among authorities knowledgeable in the fields of food science (safety and nutrition); clinical research; veterinary medicine; pharmacology; toxicology; biostatistics; medical devices; public health and epidemiology; product manufacturing and quality; and other scientific areas relevant to FDA regulated products such as systems biology, informatics, nanotechnology, and combination products.

*Ensuring Fair Balance:*

Appointments are made without discrimination. The committee is reviewed in totality for balance, characterized by inclusion of necessary knowledge, insight, and scientific perspective from the relevant community or expertise area. Nominations are sought from all geographic locations within the United States and its territories, and from diverse sources including professional and scientific societies, academia, government agencies, industry and trade associations, consumer and patient organizations, and current Agency staff.

4. *List of all other Federal advisory committees of the agency:*

*FDA maintains the following Federal advisory committees:*

Anesthetic and Analgesic Drug Products Advisory Committee
Antimicrobial Drugs Advisory Committee
Blood Products Advisory Committee
Cardiovascular and Renal Drugs Advisory Committee
Cellular Tissue and Gene Therapies Advisory Committee
Dermatologic and Ophthalmic Drugs Advisory Committee
Device Good Manufacturing Practice Advisory Committee
Digital Health Advisory Committee
Drug Safety and Risk Management Advisory Committee
Endocrinologic and Metabolic Drugs Advisory Committee
Gastrointestinal Drugs Advisory Committee
Genetic and Metabolic Disease Advisory Committee
Medical Devices Advisory Committee
National Mammography Quality Assurance Advisory Committee (Administratively Inactive)
Nonprescription Drugs Advisory Committee
Oncologic Drugs Advisory Committee
Patient Engagement Advisory Committee
Pediatrics Advisory Committee
Peripheral and Central Nervous System Advisory Committee
Pharmacy Compounding Advisory Committee
Psychopharmacologic Drugs Advisory Committee
Pulmonary-Allergy Drugs Advisory Committee
Risk Communication Advisory Committee (Administratively Inactive)
Technical Electronic Product Radiation Safety Standards Committee
Tobacco Products Advisory Committee

5. *Justification that the information or advice provided by the Federal advisory committee or subcommittee is not available from another Federal advisory committee, another Federal Government source, or any other more cost-effective and less burdensome source:*

The Committee advises and informs the Commissioner or designee(s) in discharging responsibilities as they relate to helping ensure safe and effective drugs and biologic products for human use, and as required, any other product for which the FDA has regulatory responsibility.

The topics considered by the Science Board require specialized expertise in specific complex scientific and technical issues that is not within the primary scope of other FDA advisory committees. As such, these issues cannot be appropriately addressed by another standing committee without diminishing the depth and relevance of the expert input provided to the Agency. The Science Board is currently FDA's only advisory committee that has the requisite expertise to address issues associated with food, cosmetic, or veterinary products, and its continuation is necessary to allow the FDA to receive outside expert scientific advice in those areas.

6. *If the consultation is a committee renewal, a summary of the previous accomplishments of the committee and the reasons it needs to continue:*

*Summary of Previous Accomplishments:*

The Science Board serves the public interest by providing scientific support for the regulation of certain products and making appropriate recommendations to the Commissioner.

On October 7, 2024, the Science Board met to receive an update from the New Alternative Methods subcommittee and hear details about the FDA's reorganization scheduled for implementation on October 1, 2024, that included significant updates to the Office of the Chief Scientist and the creation of a unified Human Foods Program.

*Impact:* This meeting's impact was to transmit formal Science Board recommendations on New Approach Methodologies (NAMs) that later fed into FDA's NAMs roadmap and related guidance activity.

7. *Explanation of why the committee/subcommittee is essential to the conduct of agency business:*

The Science Board is currently FDA's only advisory committee that has the requisite expertise to address issues associated with food, cosmetic, or veterinary products, and its continuation is necessary to allow the FDA to receive outside expert scientific advice in those areas. The Science Board also has a unique role in providing guidance on complex scientific and regulatory issues, and this role cannot be fulfilled by any other FDA advisory committee.

In conclusion, this public interest determination documents that renewing the committee is in the public interest, essential to the conduct of agency business, and that the information to be obtained is not already available through another advisory committee or source within the Federal Government.

This notice is issued under the Federal Advisory Committee Act as amended (5 U.S.C. 1001 *et seq.*). For general information related to FDA advisory committees, please visit us at

*http://www.fda.gov/Advisory Committees/default.htm.*

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No FDA–2026–N–5829]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Extralabel Drug Use in Animals

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements associated with extralabel drug use in animals.

**DATES:** Either electronic or written comments on the collection of information must be submitted by August 17, 2026.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 17, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for Written/Paper Submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

*Instructions:* All submissions received must include the Docket No. FDA–2026–N–5829 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Extralabel Drug Use In Animals.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **CONFIDENTIAL SUBMISSIONS**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

**FOR FURTHER INFORMATION CONTACT:** Kelly Covington, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–402–5661, *PRAStaff@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical