NDA 211448/S-001

TENTATIVE APPROVAL

CMG Pharmaceutical Co.
C/O Premier Research Consulting LLC
Attn: Tony Phillips
Project Manager, Premier Consulting
8000 Jarvis Ave, Suite 100
Newark, CA 94560

Dear Tony Phillips:

Please refer to your supplemental new drug application (sNDA) dated and received October 1, 2025, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for (FD&C Act) Mezofy (aripiprazole) oral film.

(b) (4)

We have completed our review of this application, as amended. It is tentatively approved under 21 CFR 314.105(a); therefore, this application is not approved and will not be approved until FDA issues an approval letter after any necessary additional review of the application. Enclosed are the tentatively approved labeling (text for the Prescribing Information and Medication Guide**)**. This tentative approval determination is based upon information available to the Agency at this time (i.e., information in your application and the status of current good manufacturing practices of the facilities used in the manufacture and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention.

Your application contains a certification to a patent under section 505(b)(2)(A)(iv) of the FD&C Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of, this drug product under this application ("Paragraph IV certification"). Section 505(c)(3)(C) of the FD&C Act provides that approval of a new drug application submitted pursuant to section 505(b)(2) of the FD&C Act shall be made effective immediately, unless an action is brought for infringement of one or more of the patents that were the subject of the paragraph IV certification. This action must be taken prior to the expiration of 45 days from the date the notice provided under section 505(b)(3) is received by the patent owner/approved application holder. You notified us that you complied with the requirements of section 505(b)(3) of the FD&C Act.

However, because the 45-day period described in section 505(c)(3)(C) of the FD&C Act has not yet expired, final approval cannot be granted at this time.

To obtain final approval of this application, submit an amendment two or six months prior to the date you believe that your NDA will be eligible for final approval, as appropriate. In your cover letter, clearly identify your amendment as **"REQUEST FOR FINAL APPROVAL"**. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of any relevant court order or judgment settlement, or licensing agreement, as appropriate. In addition to a safety update, the amendment should also identify changes, if any, in the conditions under which your product was tentatively approved, i.e., updated labeling; chemistry, manufacturing, and controls data; and risk evaluation and mitigation strategy (REMS). If there are no changes, clearly state so in your cover letter. Any changes require our review before final approval and the goal date for our review will be set accordingly.

Until we issue a final approval letter, this supplemental NDA is not approved, and the use of the enclosed tentatively approved labeling is not permitted for marketing the drug product. If you believe that there are grounds for issuing the final approval letter before the expiration of the patent(s), you should amend your application accordingly.

If you have any questions, contact Pawanprit (Pinky) Singh, Regulatory Project Manager, at Pawanprit.singh@fda.hhs.gov or 240-402-8866.

Sincerely,

{See appended electronic signature page}

Tiffany R. Farchione, MD
Director
Division of Psychiatry
Office of Neuroscience
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S): (tentatively approved)

- Content of Labeling
  - Prescribing Information
  - Medication Guide

52 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

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This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

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