NDA 218637

NDA APPROVAL

Kamat Pharmatech, LLC
Attention: Madhav S. Kamat, PhD, RPh
Chief Executive Officer
685 US Highway 1
North Brunswick, NJ 08902

Dear Dr. Kamat:

Please refer to your new drug application (NDA) dated January 27, 2024, received January 29, 2024, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Raldesy (trazodone hydrochloride) oral solution.

This NDA provides for the use of Raldesy (trazodone hydrochloride) oral solution for the treatment of major depressive disorder (MDD) in adults.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Instructions for Use, and Medication Guide) as well as annual

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

reportable changes not included in the enclosed labeling. Information on submitting SPL files using eLIST may be found in the guidance for industry, *SPL Standard for Content of Labeling Technical Qs and As* (October 2009).

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the container labeling submitted on November 13, 2024, and carton labeling submitted on November 25, 2024, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry, *SPL Standard for Content of Labeling Technical Qs & As.* For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved NDA 218637**." Approval of this submission by FDA is not required before the labeling is used.

DATING PERIOD

Based on the stability data submitted to date, the expiry dating period for Raldesy (trazodone hydrochloride) oral solution shall be 24 months from the date of manufacture when stored at 20° to 25°C.

The expiration date for the packaged product, Raldesy (trazodone hydrochloride) oral solution plus oral dosing syringe and bottle adaptor, shall be dependent on the shortest expiration date of any component.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA; 21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages younger than 7 years because necessary studies are impossible or highly impracticable. This is because of the low prevalence of MDD in this age group.

We are deferring submission of your pediatric studies for ages 13 years to 17 years for this application because this product is ready for approval for use in adults and the pediatric studies have not been completed and for ages 7 years to 12 years for this

application because pediatric studies in this age group should be delayed until additional safety or effectiveness data have been collected.

Your deferred pediatric studies required by section 505B(a) of the FDCA are required postmarketing studies. The status of these postmarketing studies must be reported annually according to 21 CFR 314.81 and section 505B(a)(4)(C) of the FDCA. These required studies are listed below.

4725-1 Conduct a juvenile animal study to assess the safety of Raldesy in animals of an age range and stage of development that are comparable to the population of children 7 to 12 years.

Final Protocol Submission: 02/2025
Study Completion: 11/2025
Final Report Submission: 01/2027

4725-2 Conduct a randomized, double-blind, placebo-controlled study to assess the safety, efficacy, and pharmacokinetics of Raldesy for the treatment of major depressive disorder in adolescents 13 through 17 years of age.

Final Protocol Submission: 02/2025
Study Completion: 09/2027
Final Report Submission: 03/2028

4725-3 Conduct a randomized, double-blind, placebo-controlled study to assess the safety, efficacy and pharmacokinetics of Raldesy for the treatment of major depressive disorder in a mixed child and adolescent population 7 through 17 years of age.

Draft Protocol Submission: 04/2027
Final Protocol Submission: 07/2027
Study Completion: 12/2030
Final Report Submission: 06/2031

FDA considers the term *final* to mean that the applicant has submitted a protocol, the FDA review team has sent comments to the applicant, and the protocol has been revised as needed to meet the goal of the study or clinical trial.[2]

Submit the protocol(s) to your IND 143176, with a cross-reference letter to this NDA. Reports of these required pediatric postmarketing studies must be submitted as an NDA or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting

[2] See the guidance for Industry, *Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act* (October 2019). https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry, *Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs* (April 2022).

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at FDA.gov.[3] Information and Instructions for completing the form can be found at FDA.gov.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

Your product is a Part 3 combination product (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an approved combination product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at FDA.gov.[4]

COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standards for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website.[5]

[3] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[4] https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products
[5] https://www.uspnf.com/

If you have any questions, contact Sarah Seung, Senior Regulatory Project Manager, at sarah.seung@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Bernard Fischer, MD
Deputy Director
Division of Psychiatry
Office of Neuroscience
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide
  - Instructions for Use
- Carton and Container Labeling

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/

BERNARD A FISCHER
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