NDA 218328

TENTATIVE APPROVAL

Seasons Biotechnology (Taizhou) Co., Ltd.
C/O Milestone Biopharm, LLC
Attention: Weiping Dong
President
9246 Fox Sparrow Road
Tampa, FL 33626

Dear Weiping Dong:

Please refer to your new drug application (NDA) dated and received April 19, 2023, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Sehippy (vortioxetine) orally disintegrating tablets.

(b) (4)

We have completed our review of this application. It is tentatively approved under 21 CFR 314.105(a); therefore, it is not approved and will not be approved until FDA issues an approval after any necessary additional review of the NDA. Enclosed are the tentatively approved labeling (text for the Prescribing Information, Medication Guide, and carton and container labeling). 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.

Final approval of your application is subject to expiration of a period of patent protection and/or exclusivity. Therefore, final approval of your application may not be granted before the period has expired.

To obtain final approval of this application, submit an amendment 2 or 6 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 NDA is not approved.

This drug product not approved and cannot be legally marketed until you have been notified in writing that this NDA is approved. The use of the enclosed tentatively approved labeling is not permitted for marketing this drug product.

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 note that if this application is ultimately approved, you will need to meet these requirements.

If you have any questions, contact Sujin Wolff, Regulatory Project Manager, at Sujin.Wolff@fda.hhs.gov or 301-796-1519.

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): (tentatively approved)

- Content of Labeling
  - Prescribing Information
  - Medication Guide
  - Carton and Container Labeling

36 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/

BERNARD A FISCHER
02/16/2024 03:58:33 PM