



NDA 203109/S-019

APPROVAL LETTER

Viatrix Specialty LLC
Attention: Dr. Shan Lu
Regulatory Strategist Director
3711 Collins Ferry Road
Morgantown, WV 26505

Dear Dr. Shan Lu:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 1, 2024, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Revatio (sildenafil) suspension.

This “Changes Being Effectuated in 30 days” supplemental new drug application provides to remove the 0.5mL and add 1mL marker on the oral syringe.

APPROVAL & LABELING

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

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 <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the prescribing information, and instructions for use) with the addition of any labeling changes in pending “Changes Being Effectuated” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled *SPL Standard for Content of Labeling Technical Qs and As* at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format,

that includes the changes approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Grafton Adams, Senior Regulatory Business Process Manager, at grafton.adams@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Gurpreet Gill-Sangha, Ph.D.
Supervisor
Division of Product Quality Assessment II
Office of Product Quality Assessment I
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):
Content of Labeling



Gurpreet
Gill Sangha

Digitally signed by Gurpreet Gill Sangha
Date: 10/25/2024 04:16:27PM
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