NDA 021845/S-028

SUPPLEMENT APPROVAL

Viatris Specialty LLC
Attention: Robert Barto
Senior Director Regulatory Affairs
3711 Collins Ferry Road
Morgantown, WV 26505

Dear Mr. Barto:

Please refer to your supplemental New Drug Application(s) (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA), and all amendments, for the following products:

Supplemental Application	Product Information	Submit Date	FDA Received Date
NDA 021845/S-028	Revatio (sildenafil citrate) tablet, film coated	June 21, 2024	June 21, 2024
NDA 022473/S-019	REVATIO (SILDENAFIL CITRATE)	June 21, 2024	June 21, 2024

These "Changes Being Effected" supplemental new drug applications provide for Revising labeling to combine within a single Prescribing Information, Patient Information and Instructions for Use of the three dosage forms of REVATIO® (NDA-021845 for tablets, NDA-022473 for injection and NDA-203109 for powder for oral suspension) to be consistent with labeling of NDA 203109/S-019 (Powder for Oral Suspension).

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are 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 Effected” (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/DrugsGuidanceComplianceRegulatoryInformation/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 these supplemental applications, 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).
is used.

REPORTING REQUIREMENTS

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

If you have any questions, call Grafton Adams, Regulatory Business Process Manager, at (240) 402 - 7765.

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:

Content of Labeling

Gurpreet
Gill Sangha

Digitally signed by Gurpreet Gill Sangha
Date: 12/16/2024 12:45:38PM
GUID: 5135f2ad000117842392c50c36c7f28a