BLA 022210/S-027

SUPPLEMENT APPROVAL

Zenpep, LLC
Attention: Vandana Garikipati, PhD
Vice President, Head of Global Regulatory Affairs Pharma
1007 US Hwy 202/206
Bldg JR2
Bridgewater, NJ 08807

Dear Dr. Garikipati:

Please refer to your supplemental biologics license application (sBLA) dated and received April 28, 2023, and your amendments, submitted under section 351(a) of the Public Health Service Act for Zenpep (pancrelipase) delayed-release capsules.

This Prior Approval sBLA provides for an addition of a unit strength of Zenpep (pancrelipase) delayed-release capsules, containing 60,000 USP units of lipase, manufactured at (b) (4), with corresponding labeling changes.

APPROVAL & LABELING

We have completed our review of this sBLA, 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, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at FDA.gov[1], that is identical to the enclosed labeling (text for the prescribing information, and Medication Guide) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements.

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 BLA, including pending "Changes Being Effected" (CBE) supplements,

for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] in MS Word format that includes the changes approved in this supplemental application.

CARTON AND CONTAINER LABELS

We acknowledge your August 15, 2023, submission containing final printed carton and container labeling.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, 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(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

If you have any questions, contact Musse Olani, Pharm.D., Regulatory Business Process Manager, at musse.olani@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Yan Wang, Ph.D.
Supervisory Biologist
Review Chief
Division of Biotechnology Review and Research II
Office of Biotechnology Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):

Content of Labeling
Container Labeling

Yan Wang (OPQ/OBP)

Digitally signed by Yan Wang (OPQ/OBP)
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