



BLA 022523/S-016

## **SUPPLEMENT APPROVAL**

Vivus, Inc.  
Attention: Santosh Varghese, MD  
Chief Medical Officer  
900 East Hamilton Ave  
Suite 550  
Campbell, CA 95008

Dear Dr. Varghese:

Please refer to your Supplemental Biologics License Application (sBLA) dated October 30, 2020, received October 30, 2020, and your amendments, submitted under section 351(a) of the Public Health Service Act for Pancreaze (pancrelipase) delayed-release capsules.

We also refer to our approval letter dated April 26, 2021, which contained the following error: The paragraph stating “This Prior Approval sBLA proposes the introduction of a new dosage strength for Pancreaze of 37,000 USP lipase units” should have read “This Prior Approval sBLA proposes the introduction of a new dosage strength for Pancreaze of 37,000 USP lipase units and revised labeling to ensure conformity with requirements for biological products regulated under section 351 of the PHS Act.” Also, the revised date on the enclosed content of labeling “Revised: XX/2020” should have read “Revised: 04/2021.”

This replacement approval letter incorporates the correction of the error. The effective approval date will remain April 26, 2021, the date of the original approval letter.

This Prior Approval sBLA proposes the introduction of a new dosage strength for Pancreaze of 37,000 USP lipase units and revised labeling to ensure conformity with requirements for biological products regulated under section 351 of the PHS Act.

### **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, 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](http://FDA.gov)<sup>1</sup>, that is identical to the enclosed labeling (text for the prescribing information)

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 *SPL Standard for Content of Labeling Technical Qs and As*<sup>2</sup>

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 Microsoft Word format that includes the changes approved in this supplemental application, as well as annual reportable changes. 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).

### **CARTON AND CONTAINER LABELING**

We acknowledge your April 15, 2021, submission containing final printed carton and container labeling.

This information will be included in your biologics license application file.

If you have any questions, call Melinda Bauerlien, Senior Regulatory Business Process Manager, at (301) 796 - 0906.

Sincerely,

*{See appended electronic signature page}*

Amy Rosenberg, M.D.  
Director  
Division of Biotechnology Review and Research III  
Office of Biotechnology Products  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research

<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

<sup>2</sup> We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

Enclosure(s):

Content of Labeling

Carton and Container Labeling



Maria  
Gutierrez Lugo

Digitally signed by Maria Gutierrez Lugo  
Date: 11/02/2021 03:58:31PM  
GUID: 50757b3d000038f82ef48db08ba1ceea