DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022523/S-004

FULFILLMENT OF POSTMARKETING REQUIREMENT
SUPPLEMENT APPROVAL

Janssen Pharmaceuticals, Inc.
c/o Janssen Pharmaceutical Research & Development, LLC
Attention: Ilona Scott
Director, Global Regulatory Affairs
920 Route 202 South
Raritan, NJ 08869

Dear Ms. Scott:

Please refer to your Supplemental New Drug Application (sNDA) dated and received September 16, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Pancreaze (pancrelipase) Delayed-Release Capsules.

We acknowledge receipt of your amendments dated October 10, 2013, November 7, 2013, December 4, 2013, December 23, 2013, February 21, 2014, February 25, 2014, and February 26, 2014.

This "Prior Approval" supplemental new drug application provides for an additional dosage strength of 2,600 USP lipase units.

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 text.

As provided under 21 CFR 314.70(e), approval of a protocol may justify a reduced reporting category for a particular change. If the results of the process validation study conducted to support the filling step for the 2,600 U USP Lipase/cps product meet the requirements specified in your approved protocol, it should be reported in your annual report (21 CFR 314.70(d)). This report should include the information described in 21 CFR 314.70(d)(3).

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 and labeling submitted on February 25,

2014 (text for the package insert, Medication Guide), 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 from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes 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).

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the carton and immediate-container labels submitted on September 16, 2013, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 022523/S-004**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

FULFILLMENT OF POSTMARKETING REQUIREMENT(S)/COMMITMENT(S)

We have reviewed your submission and conclude that the following requirement was fulfilled.

REQUIRED PEDIATRIC ASSESSMENTS

1629-1 Deferred requirement for development of an age appropriate formulation for PANCREAZE (pancrelipase) Delayed-Release Capsules to allow for dosing to the youngest, lowest weight pediatric patients, including infants less than 12 months of age who will be administered 2,000 to 4,000 lipase units per

120 mL of formula or per breast-feeding. Submit a supplement for an age appropriate formulation by October, 2012.

We remind you that there are postmarketing requirements(s) AND postmarketing commitment(s) in the April 12, 2010 Approval letter that are still open.

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 Mary Chung, Regulatory Project Manager, at (301) 796-0260.

Sincerely,

{See appended electronic signature page}

Andrew Mulberg, M.D.
Deputy Division Director
Division of Gastroenterology and Inborn Errors Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ANDREW E MULBERG
03/07/2014