Janssen Research & Development, LLC
Global Regulatory Affairs

17 September 2013

Donna Griebel, MD, Director
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Gastroenterology and Inborn Errors Products
Document Control Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

NDA 22-523
PANCREAZE® (pancrelipase) Delayed Release Capsules

RESPONSE TO PREA NON-COMPLIANCE LETTER

PRIVILEGED AND CONFIDENTIAL

Dear Dr. Griebel:

On 06 August 2013, the FDA issued a "Notification of Non-compliance with PREA" to PANCREAZE® (pancrelipase) Delayed Release Capsules NDA 22-523 for failure to meet the requirement of the Pediatric Research Equity Act (PREA) because Janssen had not yet submitted a pediatric assessment, which was deferred until 30 October 2012. The PREA requirement is:

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.

Under the provisions of section 505B(d) of the Federal Food, Drug, and Cosmetic Act as amended by the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), Janssen is responding herein to the Non-compliance Letter.

We also reference interactions and correspondence with the FDA on 19 October 2012, 23 November 2012, 04 January 2013, 14 January 2013, 07 March 2013, 16 April 2013, and 23 July 2013 related to Janssen's request for a Deferral Extension during which time activities were ongoing to resolve an intellectual property issue that would enable JRD to submit and seek approval of the pediatric product formulation supplemental NDA without risk of an enforcement action.

As previously communicated in updates with the FDA, Janssen Research & Development, LLC (JRD) had a completed CMC dossier for submission of the pediatric product formulation supplemental NDA (sNDA), however, JRD became aware of intellectual property owned by a third party that could have put JRD at risk of an enforcement action concerning JRD's pediatric product formulation.

JRD is in good faith negotiations with the intellectual property holder to resolve those issues and will update the Agency as these negotiations proceed.

We herein wish to inform the FDA that, on behalf of Janssen Pharmaceuticals, Inc., JRD submitted the pediatric formulation sNDA, to fulfill the PREA requirement, PMR 1629-1, on 16 September 2013.

This submission is provided in electronic format. JRD utilizes either McAfee VirusScan Enterprise or Microsoft ForeFront Client Security to ensure that this submission is free of computer viruses and spyware. JRD authorizes the CDER to use similar software as appropriate.

Should you have any questions regarding this submission or require additional information, please contact me at (908) 927-3223 or iscott1@its.jnj.com.

Sincerely,

ILONA SCOTT

Digitally signed by ILONA SCOTT
DN: c=US, o=JNJ, ou=Employees, ou=164100, cn=ILONA SCOTT, email=IScott1@its.jnj.com
Reason: I am approving this document.
Date: 2013.09.15 18:05:42 -04'00'

Ilona J. Scott
Director, Global Regulatory Affairs
Janssen Research & Development, LLC

cc: Lynne P. Yao, MD, CDER Pediatric and Maternal Health Staff