DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022210/S-009/S-012

SUPPLEMENT APPROVAL

Aptalis Pharma Limited
Attention: David Ellis, Ph.D.
Vice President, Regulatory Affairs
100 Somerset Corporate Boulevard
Bridgewater, NJ 08807

Dear Dr. Ellis:

Please refer to the below Supplemental New Drug Applications (sNDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zenpep (pancrelipase) delayed-release capsules.

NDA/Supplement	Submission Date	Received Date
NDA 022210/S-009	July 14, 2011	July 15, 2011
NDA 022210/S-012	December 15, 2011	December 16, 2011

We acknowledge receipt of your amendments dated July 28, 2011 and March 15, 2013 to NDA 022210/S-009; and January 3, 2012, December 21, 2012, and March 15, 2013 to NDA 022210/S-012.

These supplemental new drug applications provide for the following changes:

NDA 022210/S-009 ("Changes Being Effected" supplement):

- updates section 6.2 ADVERSE REACTIONS-Postmarketing Experience with postmarketing data since the launch of Zenpep in 2009
- clarifies text in section 12.1 CLINICAL PHARMACOLOGY-Mechanism of Action
- updates section 17.1 PATIENT COUNSELING INFORMATION-Dosing and Administration to notify healthcare professionals if the patient has a history of abnormal glucose levels before initiating Zenpep treatment
- adds a new section 17.4 PATIENT COUNSELING INFORMATION-Pregnancy and Breast Feeding

NDA 022210/S-012 ("Prior Approval" supplement):

- addition of information to the Storage and Handling section of the package insert label

- removal of the statement “Pharmacists: Dispense in original container” from the carton and container labeling
- updates the package insert label, Medication Guide, and carton and container labeling to reflect the new company name and address

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 text.

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 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 container labels that are identical to the carton and immediate container labels submitted on December 21, 2012, 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 titled “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 "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 022210/S-012**." Approval of this submission by FDA is not required before the labeling 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 Jagjit Grewal, Regulatory Project Manager, at (301) 796-0846.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director for Safety
Division of Gastroenterology and Inborn Errors Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: 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/

JOYCE A KORVICK
04/11/2013