DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205739/S-001

SUPPLEMENT APPROVAL

Relypsa, Inc.
Attention: Sarah McNulty
Vice President, Regulatory Affairs
700 Saginaw Drive
Redwood City, CA 94063

Dear Ms. McNulty:

Please refer to your Supplemental New Drug Application (sNDA) dated November 13, 2015, received November 13, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Veltassa (Patiromer Sorbitex Calcium) Powder for Oral Suspension, 8.4 g, 16.8 g, and 25.2 g.

This Prior Approval supplemental new drug application proposes to revise preparation instructions provided in the Prescribing Information, the Medication Guide, and the Carton and Container labels.

The following changes were made to the Prescribing Information:

1. Section 2.3, Preparation of Veltassa: The preparation instructions were simplified to facilitate patients' understanding of the instructions.
2. Section 14.2, One-Year Study: A portion of the last sentence was revised to address a typographical error and undo a round-up of the higher dose.
3. Figure 3, Mean (95% Cl) Serum Potassium over Time: The legend describing the serum K^+ ranges was revised to show the correct range.

The following changes were made to the Medication Guide:

1. How should I take Veltassa, To mix a dose of Veltassa, 3rd bullet point: The mixing instructions were edited to be consistent with the Prescribing Information and aid in patients' understanding of the instructions.
2. What are the possible side effects of Veltassa: Minor editorial changes were made.
3. How should I store Veltassa: This section was added.

The following changes were made to the Carton and Container labels:

1. The Directions for Use were revised to include complete dosing instructions consistent with the Prescribing Information.

APPROVAL & LABELING

We have completed our review of this supplemental application. It is 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 and 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

We acknowledge your May 19, 2016, submission containing final printed carton and container labels.

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, please contact Sabry Soukehal, Regulatory Health Project Manager, at (240) 402-6187.

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation 1
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling
Carton and Container Labeling

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

/s/

NORMAN L STOCKBRIDGE
05/20/2016