DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 203284/S-01

SUPPLEMENT APPROVAL

Hyperion Therapeutics
Attention: Klara A. Dickinson-Eason
SVP, Chief Regulatory Officer and Corporate Quality
2000 Sierra Point Parkway, Suite 400
Brisbane, CA 94005

Dear Ms. Dickinson-Eason:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 6, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ravicti (glycerol phenylbutyrate) Oral Liquid.

This "Prior Approval" supplemental new drug application provides for the following revised langue in Section 8.3 Nursing Mothers:

> Breastfeeding is not recommended with maternal use of RAVICTI. It is not known whether RAVICTI or its metabolites are present in breast milk. Because many drugs are present in breast milk and because of the potential for tumorigencity of glycerol phenylbutyrate identified in animal studies, as well as the potential for serious adverse reactions in nursing infants from RAVICTI, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into consideration the importance of the drug to the health of the mother *[see Use in Specific Populations (8.4) and Nonclinical Toxicology (13.1)]*.

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).

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 Jessica Benjamin, Regulatory Project Manager, at (301) 796-3924.

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
06/24/2014