



NDA 22181/S-019
NDA 205065/S-005

SUPPLEMENT APPROVAL

BioMarin Pharmaceutical Inc.
Attention: Elizabeth Moyle
Executive Director, Regulatory Affairs Global Labeling
105 Digital Drive
Novato, CA 94949

Dear Ms. Moyle:

Please refer to your supplemental New Drug Applications (NDAs) dated April 26, 2019, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Kuvan (sapropterin dihydrochloride) tablets and Kuvan (sapropterin dihydrochloride) powder for oral solution.

These “Changes Being Effected” supplemental NDAs administratively update both NDAs with the current approved Kuvan labeling, including Prescribing Information, Patient Information and Instructions for Use.

APPROVAL & LABELING

We 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 Prescribing Information, Patient Package Insert and Instructions for Use), 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 include 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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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, contact LCDR Hong Vu, Regulatory Project Manager, at (301) 796-7401.

Sincerely,

{See appended electronic signature page}

Lisa M. Soule, M.D.
Associate Director
Division of Gastroenterology and Inborn Errors
Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURES:

Content of Labeling
Prescribing Information
Patient Package Insert
Instructions for Use

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

LISA M SOULE
05/02/2019 03:49:02 PM