BLA 020772/S-027

SUPPLEMENT APPROVAL

QOL Medical, LLC
Attention: Weng Tao, M.D.
Chief Operating Officer
3405 Ocean Drive
Vero Beach, FL 32963

Dear Dr. Tao:

Please refer to your supplemental biologics license application (sBLA), dated February 18, 2021, received February 19, 2021, and your amendments, submitted under section 351(a) of the Public Health Service Act for Sucraid (sacrosidase) oral solution.

We acknowledge receipt of your amendment dated November 19, 2021, which constituted a complete response to our June 18, 2021, action letter.

This Prior Approval supplemental biologics application provides for:

- Addition of a new Sucraid (sacrosidase) oral solution 2 mL single-use container.
- Addition of (b) (4) for manufacturing, in-process testing, labeling, packaging, and storage of Sucraid (sacrosidase) oral solution 2 mL single-use container.
- Addition of a new drug product manufacturing process at (b) (4) to manufacture Sucraid (sacrosidase) oral solution 2 mL single-use containers.
- Addition of *Burkholderia cepacia* complex (Bcc) testing to the drug product release specification performed at QOL (b) (4).
- Revisions to the Dosage and Administration section of the Sucraid Prescribing Information to add instructions for preparation and administration of the recommended dosage of sacrosidase using the 2 mL single-use container.
- Other revisions to the Sucraid labeling to conform to the labeling requirements for biological products regulated under section 351 of the PHS Act.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at FDA.gov,[1] that is identical to the enclosed labeling (text for the Prescribing Information, Patient Package Insert, Instructions for Use) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this BLA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] 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).

CARTON AND CONTAINER LABELING

We acknowledge your March 25, 2002, May 5, 2022, and May 19, 2022, submissions containing final printed carton and container labeling.

For information on FDA's compliance policy for requirements related to BLA-specific labeling revisions, see guidance for industry, *The "Deemed to be a License" Provision of the BPCI Act: Questions and Answers*.[3]

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[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

[3] Available at: https://www.fda.gov/media/119274/download. For the most recent version of a guidance, check the FDA Guidance Documents Database at https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

POSTMARKETING COMMITMENTS NOT SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitment:

> PMC-4251: Provide real world shipping validation studies (including winter and summer studies) for the finished drug product from (b) (4) .

The timetable you submitted on March 7, 2022, states that you will conduct this study according to the following schedule:

> Final Report Submission: 07/2023

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs.*[4]

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

[4] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.

If you have any questions, contact Kelly Richards, Senior Regulatory Health Project Manager, at (240) 402-4276 or email at kelly.richards@fda.hhs.gov

Sincerely,

{See appended electronic signature page}

Juli Tomaino, MD, MS
Deputy Director
Division of Gastroenterology
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert
  - Instructions for Use
- Carton and Container Labeling

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/

JULI A TOMAINO
05/25/2022 10:02:10 AM