DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-772/S-011

**REMS ASSESSMENT ACKNOWLEDGEMENT-
NO DISCUSSION WARRANTED
SUPPLEMENT APPROVAL**

QOL Medical, LLC
Attention: Dayton T. Reardan, Ph.D, RAC
Agent on behalf of QOL Medical, LLC
3033 Campus Drive, Suite W125
Plymouth, MN 55441

Dear Dr. Reardan:

Please refer to your Supplemental New Drug Application (sNDA) dated September 10, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Sucraid (sacrosidase) Oral Solution, 8,500 IU/ml.

We acknowledge receipt of your first risk evaluation and mitigation strategy (REMS) assessment, which was included in your submission. After consultation between the Office of Surveillance and Epidemiology and the Office of New Drugs, we have found the REMS assessment to be adequate.

This supplemental new drug application also proposes that FDA no longer require a REMS for Sucraid (sacrosidase) Oral Solution.

We completed our review of this supplemental application. It is approved, effective on the date of this letter.

## RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Sucraid (sacrosidase) was originally approved on November 20, 2008. The REMS consists of a communication plan, elements to assure safe use, an implementation system, and a timetable for submission of assessments of the REMS. The goal of the REMS was to communicate a specific manufacturing change (b) (4) in the final product and to ascertain whether there was any increase in allergy-related adverse events following the manufacturing change. Your REMS assessment showed that there have been no reports of adverse events from the patient mailings, telephone survey, and physician surveys that were conducted as part of the REMS. You propose that FDA no longer require a REMS for Sucraid (sacrosidase) Oral Solution.

We have determined that the REMS is no longer necessary to ensure that the benefits of Sucraid (sacrosidase) outweigh its risks. Therefore, we agree with your proposal and a REMS for Sucraid (sacrosidase) is no longer required.

We request that you submit reports of all serious allergic reactions, both expected and unexpected, as 15-day reports to the Agency.

**LETTERS TO HEALTH CARE PROFESSIONALS**

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

**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 Matthew Scherer, Regulatory Project Manager, at (301) 796-2307.

Sincerely,

*{See appended electronic signature page}*

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

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

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/s/

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JOYCE A KORVICK
12/09/2010