DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-772/S-002

QOL Medical, LLC.
Attention: Trevor Blake
President and CEO
5400 Carillon Point
Kirkland, WA 98033

Dear Mr. Blake:

Please refer to your supplemental new drug application dated May 3, 2006, received May 8, 2006 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sucraid (sacrosidase) Oral Solution.

This "Changes Being Effected" supplemental new drug application provides for final study results for your approved comparability protocol for the following changes: manufacturing facility and container/closure change.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on May 3, 2006.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Susan Jenney, Regulatory Project Manager, at (301) 796-0062.

Sincerely,

{See appended electronic signature page}

Hasmukh B. Patel, Ph.D.
Branch Chief
Branch VIII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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

/s/

Hasmukh Patel

11/3/2006 02:42:38 PM