



(b) (4)

QOL Medical, LLC  
3405 Ocean Drive  
Vero Beach, FL 32963

**RE: BLA 020772**  
Sucraid® (sacrosidase) Oral Solution  
MA 553

Dear (b) (4):

The Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) has reviewed the promotional communications, Pediatric Try Sucraid Email (SUC25.1057 Rev.0725) and the Adult Try Sucraid Email (SUC25.1058 Rev.0725) (emails) for Sucraid® (sacrosidase) Oral Solution (Sucraid) submitted by QOL Medical, LLC, under cover of Form FDA 2253. FDA has determined that the emails are false or misleading. Thus the emails misbrand Sucraid and make the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The emails include the following claims and presentations (emphasis original):

- **“Try Sucraid®”**
- **“Do you have patients suffering with unresolved IBS-like symptoms, including gas, bloating, diarrhea, and/or nausea?”**
- **“Could it be CSID?”**
- “Learn more about the only FDA-approved enzyme replacement therapy for the treatment of CSID...”

These claims and presentations create a misleading impression about the indication for Sucraid. Specifically, they imply that because of overlapping symptoms with Congenital Sucrase-Isomaltase Deficiency (CSID), Sucraid can be used to treat irritable bowel syndrome (IBS), when this is not the case. Additionally, the emails imply Sucraid can be used to treat all contributing factors of CSID, when this is not the case. Specifically, the emails fail to provide material information regarding Sucraid’s full FDA-approved indication. According to the FDA-approved prescribing information (PI), Sucraid is indicated for (emphasis added), “the treatment of **sucrase deficiency**, which is part of congenital sucrase-isomaltase deficiency (CSID), in adult and pediatric patients **5 months of age and older.**” We acknowledge that the full indication is presented at bottom of the email with the Important Safety Information; however, it is presented in small plain font, after intervening text and eye-

QOL Medical, LLC  
BLA 020772/MA 553

catching graphics and/or colors. Therefore, this is not sufficient to mitigate the misleading impression.

The emails omit material facts regarding the risks associated with Sucraid. Specifically, the following material risk information from the PI is omitted (in pertinent part, bolded emphasis original, underlined emphasis added):

## **WARNINGS**

### **Severe Hypersensitivity Reactions**

Severe hypersensitivity reactions, including wheezing, rash, and pruritus, have been reported with administration of Sucraid. Sucraid contains papain, which is associated with hypersensitivity reactions.

## **PRECAUTIONS**

### **Increased Blood Glucose Concentration in Patients with Diabetes Mellitus**

Sucraid enables the products of sucrose hydrolysis, glucose and fructose, to be absorbed and may increase blood glucose concentrations. Monitor blood glucose concentrations and adjust the diet accordingly for patients with diabetes mellitus.

### **Dietary Starch Restriction**

Sucraid does not replace isomaltase. Therefore, patients may still experience symptoms of CSID while taking Sucraid. Consider dietary starch restriction in addition to Sucraid, especially in patients in whom symptoms are not adequately controlled by Sucraid.

Furthermore, the presentation of risk information in the emails do not appear in a sequence that discloses risk information in order of severity, and thus misleadingly minimizes the risks associated with Sucraid. Specifically, risk information pertaining to the ADVERSE REACTIONS section of the PI is presented prior to the risk information pertaining to the PRECAUTION section of the PI (i.e., Increased Blood Glucose Concentrations in Patients with Diabetes Mellitus), thereby framing the subsequent risk information as less serious.

## **Conclusion and Requested Action**

For the reasons described above, the emails misbrand Sucraid and make the distribution of the drug in violation of the FD&C Act.

This letter notifies you of our concerns and provides you with an opportunity to address them. FDA requests that QOL Medical, LLC, take immediate action to address any violations (including, for example, ceasing and desisting promotional communications that are misleading as described above).

Please submit a written response to this letter within 15 working days from the date of receipt, addressing the concerns described in this letter, listing all promotional communications (with the 2253 submission date) for Sucraid that contain representations like those described above, and explaining your plan for the discontinuation of such communications, or for ceasing distribution of Sucraid.

QOL Medical, LLC  
BLA 020772/MA 553

If you believe that your products are not in violation of the FD&C Act, please include in your submission to us your reasoning and any supporting information for our consideration within 15 working days from the date of receipt of this letter.

The concerns discussed in this letter do not necessarily constitute an exhaustive list of potential violations. It is your responsibility to ensure compliance with each applicable requirement of the FD&C Act and FDA implementing regulations.

Please direct your response to the undersigned at the **Food and Drug Administration, Center for Drug Evaluation and Research, Office of Prescription Drug Promotion, 5901-B Ammendale Road, Beltsville, Maryland 20705-1266**. A courtesy copy can be sent by facsimile to (301) 847-8444. Please refer to MA 553 in addition to the BLA number in all future correspondence relating to this particular matter. All correspondence should include a subject line that clearly identifies the submission as a Response to Untitled Letter. You are encouraged, but not required, to submit your response in eCTD format. All correspondence submitted in response to this letter should be placed under eCTD Heading 1.15.1.6. Additionally, the response submission should be coded as an Amendment to eCTD Sequence 5255 under BLA 020772. Questions related to the submission of your response letter should be emailed to [CDER-OPDP-RPM@fda.hhs.gov](mailto:CDER-OPDP-RPM@fda.hhs.gov).

Sincerely,

{See appended electronic signature page}

Meeta Patel, Pharm.D.  
Regulatory Review Officer  
Division of Advertising & Promotion Review 2  
Office of Prescription Drug Promotion

{See appended electronic signature page}

Adewale Adeleye, Pharm.D., M.B.A.  
Team Leader  
Division of Advertising & Promotion Review 2  
Office of Prescription Drug Promotion

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**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.**

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/s/

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MEETA N PATEL  
05/26/2026 03:24:26 PM

JAMES S DVORSKY on behalf of ADEWALE A ADELEYE  
05/26/2026 03:28:18 PM