PHYSICIAN'S ACKNOWLEDGMENT FORM – LOT C1102

Physician Acknowledgment for the Distribution of SUCRAID®

Patient name (please print):_____ DOB: _____

This form is to be filled out by all Physicians prescribing Sucraid® for any patient that needs a prescription filled/refilled after [May 4, 2017]. A separate Acknowledgment Form needs to be completed for each patient prescribed Sucraid®, even if a previous Acknowledgment Form was provided for Lot A1147, A1150, B1210, B1102, B1213, C0502, C0902 or C1201.

There is a shortage of Sucraid® because the process that has been used for making Sucraid® does not meet FDA's pharmaceutical standards, including the minimum current good manufacturing practice (CGMP) requirements. Therefore, our conversion to the required process has been delayed. In addition, QOL Medical has moved the manufacture of the active ingredient in Sucraid® (sacrosidase) Oral Solution to a new facility. As a temporary measure, since Sucraid® is in shortage, QOL is coordinating with FDA to provide patients with Sucraid® from an unapproved Lot C1102. This lot C1102 of Sucraid® was manufactured at the unapproved facility under conditions that do not yet meet FDA standards for pharmaceuticals.

FDA's standards for pharmaceuticals are designed to maintain consistency in products and to minimize potential contamination from microbes like bacteria that can get into the product during its manufacture. As the facility and process are not fully approved and additional testing or improvements are required, there is a potential risk that the final drug product may contain bacterial byproducts. These possible bacterial byproducts could be a safety concern for some people, such as those who are immunocompromised. There is a chance that Sucraid® from this lot may cause symptoms in some patients, such as vomiting and diarrhea.

Please promptly report any adverse events such as diarrhea, vomiting, or any unexpected adverse events to us and to the FDA. If you have evaluated the potential risks against the benefits of this product and any alternate treatments, and believe that your patient should start or continue taking Sucraid®, please complete this form and provide it to Sucraid*ASSIST*™ as soon as possible.

By signing below you acknowledge that:

- You understand the potential safety risks outlined above;
- You or a member of your clinical staff have explained to the patient with sucrase-isomaltase deficiency (CSID) or his/her guardian the potential risks of taking this unapproved lot C1102 of Sucraid®.
    - The patient, parent or legal guardian has given his/her signed consent to you or a member of your clinical staff to take Sucraid® made from this lot; and
- You agree to inform both the manufacturer of Sucraid®, QOL Medical LLC (Phone: 1-866-469-3773 | Fax: 772-365-3375 | Email: info@qolmed.com), and the FDA at 1-888-INFO-FDA (463-6332) of adverse events that occur while the patient is taking Sucraid®.

Physician name (please print):_____

Physician signature:_____

Physician address for correspondence (Street):_____

(City, State, Zip):_____

Physician's telephone: _____Date _____

Please fax this signed, completed form to Sucraid*ASSIST*™ at 800 632-1944.