PATIENT CONSENT FORM – LOT C1201

Important Information and Consent Form Regarding the Receipt, and Use of SUCRAID® by Patients/Legal Guardians of Patients

This form is to be read and filled out by the patient with congenital sucrase-isomaltase deficiency (CSID) or his/her legal guardian who wishes to obtain Sucraid®, which is temporarily in limited supply.

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. 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 C1201. This lot C1201 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 with a weak immune system. There is a chance that Sucraid® from this lot may cause symptoms in some patients, such as vomiting and diarrhea. Please let your doctor know immediately if you have adverse symptoms.

By signing below you acknowledge that you have had a discussion with your physician and understand the potential risks. If you are willing to receive and use Sucraid® from this lot please sign and fax a copy of this form to Sucraid*ASSIST*™ at Fax: 800-632-1944.

Your signature indicates that you consent to receive and use the Sucraid® from this lot and you understand and accept the potential safety risks described above with this unapproved lot C1201 of Sucraid®. If you do not understand the above or what this could mean to you and want more information, please contact Sucraid*ASSIST*™ at 800-705-1962 for additional information.

Patient name (please print):_____ DOB:_____

Address for correspondence (Street):_____

(City, State, Zip):_____

Telephone (Patient):_____

Signature (Patient/Legal Guardian):_____Date:_____