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 and our conversion to the required process has been delayed. We expect to finalize the process upgrade by the end of the year. As a temporary measure, since Sucraid is in shortage, the FDA has allowed the release of Sucraid lot number A1147 to patients. This lot of Sucraid was manufactured at an unapproved facility under conditions that did not 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. While this lot was not produced under FDA's pharmaceutical standards, the production process included filtration to remove potential contamination with bacteria, and test results show that the drug product in this lot does not contain actual bacteria. However, there is a potential risk that the final drug product may contain bacterial byproducts resulting from the manufacturing process of this lot. These 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 the pharmacy Accredo at Fax: 866-777-7097.

Your signature indicates that you consent to receive and use the Sucraid from this lot and you understand that Sucraid was manufactured at an unapproved facility. If you do not understand the above or what this could mean to you and want more information, please contact QOL Medical, LLC at 704 692-1634 for additional information.

Patient name (please print):_____

Address for correspondence (Street):_____

(City, State, Zip):_____

Telephone (Patient):_____

Signature (Patient/Legal Guardian):_____Date:_____