PATIENT CONSENT FORM – LOT D0402

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.

QOL Medical has moved the manufacture of the active ingredient in Sucraid® (sacrosidase) Oral Solution to a new facility and has also recently changed the process. There is a shortage of Sucraid® because QOL is still preparing their complete submission to allow FDA evaluation of the unapproved process and facility in order to confirm that these meet FDA's pharmaceutical standards, including the minimum current good manufacturing practice (CGMP) requirements. As a temporary measure, since Sucraid® is in shortage, QOL is coordinating with FDA to provide patients with Sucraid® from an unapproved Lot D0402. This lot of Sucraid® was manufactured with the unapproved process and facility under conditions that may not meet FDA standards for pharmaceuticals.

The recent changes to the manufacturing process have concentrated on reducing the potential for microbiological contamination of the active ingredient in order to reduce the risk of bacterial byproducts. In addition to the unapproved process and facility, QOL has also changed the standard of sterility for Sucraid® oral solution. As a result, Lot D0402 is not sterile, however the quantity of microorganisms in Lot D0402 has been tested and confirmed to be within the FDA recommended levels for oral drugs at all points throughout the manufacturing process. There is a potential risk that Lot D0402 may contain viable microorganisms (e.g. bacteria) and bacterial byproducts derived from the manufacturing process. These possible bacteria or bacterial byproducts could be a safety concern for some people, such as those with a weak immune system. While the quantity of microorganisms in this Lot D0402 has been tested and confirmed to be within the FDA recommended levels for oral drugs at all points throughout the manufacturing process, there is still a remote chance that Sucraid® from this Lot D0402 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 the unapproved Lot D0402 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:_____

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