PHYSICIAN'S ACKNOWLEDGMENT FORM – LOT A1150

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 November 30, 2015. A separate Acknowledgment Form needs to be completed for each patient prescribed Sucraid®, even if a previous Acknowledgment Form was provided for Lot A1147.

There is a shortage of Sucraid® because the process that has been used for making Sucraid® does not meet FDA's pharmaceutical standards, and the conversion to the required updated process has been delayed. We expect to finalize the process upgrade by the Spring of 2016. As a temporary measure, since Sucraid® is in shortage, the FDA has allowed the release of Sucraid® **lot number A1150**. This lot of Sucraid® was manufactured at an unapproved facility under conditions that did not meet FDA's 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 patients, 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 the Pharmacy identified below as soon as possible.

By signing below you acknowledge that:

- You understand the 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 Sucraid® made in the unapproved facility.
    - 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 the Accredo Pharmacy at (866)-777-7097.