PHYSICIAN'S ACKNOWLEDGMENT FORM – LOT D0401

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 June 29, 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, C1201, or C1102.

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 D0401. 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 D0401 is not sterile, however the quantity of microorganisms in Lot D0401 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 D0401 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 who are immunocompromised. While the quantity of microorganisms in Lot D0401 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 Lot D0401 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 Lot D0401 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.

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