UPDATE ON SUCRAID® PRODUCT
IMMEDIATE ACTION REQUIRED
FOR ALL SUCRAID® PRESCRIPTIONS AND REFILLS AFTER JUNE 15, 2018

Dear patients, prescribing physicians, and other healthcare providers: June 15, 2018

This letter is to update you on the limited supply of Sucraid® (sacrosidase) Oral Solution. As a temporary measure, since Sucraid® is in shortage, QOL is coordinating with FDA to provide Sucraid® from an unapproved lot D0912 to physicians and patients/legal guardians of patients who have received information, understand the potential safety risks, and consent to the use of this product.

If you want to receive a prescription for Sucraid® after June 15, 2018, you and your doctor will have to complete the forms listed below.

To continue to get a prescription for Sucraid® (which will be **lot D0912)**, you **MUST** do the following:

1. **Communicate** with your doctor about the potential safety risks with using this lot.
2. ***Patient Consent Form:*** **Patient (or parent or guardian for minor patients) sign and date** an informed consent stating that you understand and accept the potential safety risks. **Give a copy of this document to your physician and send copies to the place[s] noted below.**
3. ***Minor's Assent Form:*** **If patient is a child aged 7 to 17 years, he or she must sign and date an assent** form stating that he or she understands the risks and assents. **Give a copy of this document to your physician and send copies to the place[s] noted below.**
4. ***Physician's Acknowledgment Form:*** Have **your doctor sign and date an acknowledgement** that he or she understands the manufacturing situation, the potential safety risks with using this lot, and has communicated with you about it. **The physician must send a copy of the Acknowledgment to the place[s] noted below.**
5. ***Patient Questionnaire:*** **Patients (or parent or guardian if patient under 18) fill out a questionnaire** about the use of **lot D0912 AFTER using Sucraid® lot D0912**.

Before You Can Receive Sucraid® Lot D0912, You Must Provide the Following:			
Each form must be signed and dated.	***Patient Consent Form***	***Minor's Assent Form***	***Physician's Acknowledgement Form***
Patients Under 7 years	Parents / Guardians	Not Required	Doctor
Patients 7 to 17 years	Parents / Guardians	Patient	Doctor
Patients 18 and Older	Patient	Not Required	Doctor

Send forms:

By fax to Sucraid*ASSIST*™ and US Bioservices Specialty Pharmacy: 800-632-1944

Thank you for working with us through these steps.

For questions, please contact Sucraid® Patient Assistance Services at 800-705-1962 or US Bioservices Specialty Pharmacy at 833-800-0122.

PHYSICIAN'S ACKNOWLEDGMENT FORM – LOT D0912

-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 15, 2018. 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, C1102, D0401, D0402, D0403, D0607, D0901 or D0904.

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 D0912. 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 D0912 is not sterile, however the quantity of microorganisms in lot D0912 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 D0912 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 D0912 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 D0912 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*™ and US Bioservices Specialty Pharmacy 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 D0912 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*™ and US Bioservices Specialty Pharmacy at 800-632-1944.

150618

MINOR'S ASSENT FORM

ASSENT FORM FOR CHILDREN TAKING SUCRAID®

You are being asked to read and sign this form because you take Sucraid® for a condition that causes you to be unable to digest table sugar, which is in a lot of your foods.

The company that makes Sucraid® ran out of its regular Sucraid® last year and there is not any regular Sucraid® available. However, you can choose to take another kind of Sucraid® so that you can keep taking the drug. This Sucraid® has a specific lot number on the bottle, D0912. This other Sucraid® has been tested and is very similar to the regular Sucraid®, but there is a small chance that this other kind of Sucraid® could make you throw up or cause you to have a stomach ache that may be different from what you are used to having. If you do take this different Sucraid®, please let your doctor or your parents or other caregivers know right away if it causes you to have any problems.

If you do not want to receive this other kind of Sucraid®, you do not have to say yes or sign your name on this form. No one will be mad at you if you say no.

By signing your name, you are saying that you have talked with your doctor or your parents/caregivers about taking this other kind of Sucraid®. If you want to receive and use this other kind of Sucraid®, please sign your name.

_____ _____

Assent By Child Date

DOB:_____ Age:_____

To the Physician/Clinician/Parent obtaining the assent:

If the child does not sign the form, but you believe the child has actively assented, please document on this form. State the specific behaviors (head shake yes, child said okay after you described the procedure, etc.).

_____

_____

_____

_____ _____

Signature Date

If the child is willing to receive and use the other kind of Sucraid® and has signed or provided active assent, fax a copy of this form to Sucraid*ASSIST™* and US Bioservices Specialty Pharmacy at Fax: 800-632-1944.

PATIENT CONSENT FORM – LOT D0912

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 D0912. 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 D0912 is not sterile; however, the quantity of microorganisms in lot D0912 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 D0912 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 D0912 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 D0912 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*™ and US Bioservices Specialty Pharmacy 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 D0912 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 or US Bioservices Specialty Pharmacy at 833-800-0122 for additional information.

Patient name (please print):_____ DOB:_____

Address for correspondence (street):_____

(city, state, zip):_____

Telephone (patient):_____

Signature (patient/legal guardian):_____Date:_____

150618

TO BE FILLED OUT AFTER TAKING SUCRAID® FROM LOT NUMBER D0912 RELEASED DURING SUCRAID® SHORTAGE

PATIENT QUESTIONNAIRE

Sucraid® (sacrosidase) Oral Solution May Be Completed by the Patient or Patient's Parent or Guardian

Patient name_____ **DOB**:_____ **Phone:**_____

Parent/Guardian name (if not completed by patient) _____**Date**_____
Lot number of Sucraid®: _____**(please enter the lot number that appears on the bottle)**

1. **When did you first start taking Sucraid® (any lot)?**
   Month: _____ Year: _____

2. **Before you started taking Sucraid®, what were your main symptoms? Check all that apply.**
   - ☐ Frequent diarrhea
   - ☐ Bloating
   - ☐ Constipation
   - ☐ Weight loss
   - ☐ Excessive gassiness
   - ☐ Abdominal cramps or abdominal pain
   - ☐ Other(s) _____

3. **What is your age? _____months old OR _____years old**

4. **When did you start taking Sucraid® from this lot number D0912?**
   Month: _____Year: _____

Since you started taking the Sucraid® lot number D0912 as indicated in #4:

5. **Have you noticed any increase in your digestive symptoms (as indicated in #2) between previous lots and this lot of Sucraid®?**

   Yes ☐ No ☐

   If yes, what symptoms increased, and how many times each day did you have these symptoms?
   Symptom: _____ How many times each day_____
   Symptom: _____ How many times each day_____
   Symptom: _____ How many times each day_____

6. **Have you experienced any side effects since taking this lot of Sucraid®?**

   Yes ☐ No ☐

   If so, please describe: _____

7. **Have you noticed a change in the color of this lot of Sucraid®?**

   Yes ☐ No ☐

   If so, please describe: _____

8. **What other changes have you noticed in this lot of Sucraid®? Check all that apply.**
   - ☐ Change in taste. Please describe _____
   - ☐ Change in smell. Please describe _____
   - ☐ Change in something else. Please specify and describe _____
   - ☐ No change

9. **Have you noticed any other significant symptoms that you believe are related to this lot D0912 of Sucraid? Please describe:**_____

TO BE FILLED OUT AFTER TAKING SUCRAID® FROM LOT NUMBER D0912 RELEASED DURING SUCRAID® SHORTAGE

HIPAA Statement

Authorization to Use and Disclose Protected Health Information ("Authorization"): I authorize my pharmacy, US Bioservices Inc. (US Bio), QOL Medical, LLC, the maker of Sucraid®, One Patient Services, LLC, Sucraid® support service provider, dietary consultants, my physicians, and other healthcare providers, pharmacists, insurers, and any agent or representative of any of these parties (collectively, "Authorized Parties") to obtain individually identifiable health information ("IIHI") regarding me and my medical condition, symptoms, treatments, family medical history, insurance coverage and payment history, and diet, and to collect, use, and disclose my IIHI among each other to/from third parties (which may include insurers, public funding programs, social workers, advocacy organizations, assistance organizations, healthcare providers, dietary consultants, and other persons or entities as any of the Authorized Parties may deem appropriate) to: (1) coordinate my treatment; (2) facilitate reimbursement support and obtain payment for my treatment; (3) provide me and my healthcare providers with free educational materials, dietary support, and/or peer consultation; (4) conduct healthcare marketing activities, including those for which US Bio or One Patient Services, LLC receives compensation; (5) conduct clinical assessments regarding therapeutic response to Sucraid®; and (6) carry out any other purpose required or permitted by law. I understand that any of the Authorized Parties may need to contact me for additional information. For purposes of this authorization, I understand that my IIHI includes any individually identifiable information about me such as my social security number, contact information, medical condition or other health information, and treatment and payment history relating to my past, present, and future use of Sucraid® and other healthcare items or services. I understand that once my information is disclosed under this authorization, it may be further disclosed and no longer protected by federal confidentiality laws. I understand that treatment by my physician and payment, enrollment, or eligibility to receive Sucraid® is not conditioned upon the signing of this authorization. However, if I refuse to sign this authorization, my ability to receive support services related to my use of Sucraid® may be limited. I understand that this authorization will remain in effect until the later of ten (10) years from the date of my signature or five (5) years following my discontinuance of purchase of Sucraid® unless I revoke it by sending written notice to the One Patient Services Manager at One Patient Services, 3739 National Drive, Suite 100, Raleigh, NC 27612. If I revoke this authorization, One Patient Services, LLC will communicate my revocation to the Authorized Parties and will stop using and disclosing my information as soon as possible. However, my revocation will not affect any prior use or disclosure of IIHI made in reliance on this authorization and my revocation will not affect my treatment by my physician. If I have questions about disclosures of my IIHI, I may contact the Privacy Officer at One Patient Services at sucraid@onepatientservices.com. I understand that I have the right to receive a copy of this authorization. I further understand that I have the right at any time to refuse nursing support, dietary support, or peer consultation.

Patient Name (print)_____Date_____
Patient Signature (or representative)_____Relationship to Patient (if applicable)_____

When you have completed the questionnaire, please send the completed questionnaire by email to sucraid@onepatientservices.com or by mail (using the postage paid envelope) to the address below.

Postage paid envelope to:

One Patient Services
2018 Patient Questionnaire
3739 National Drive, Suite 100
Raleigh, NC 27612

Email to: **sucraid@onepatientservices.com**

If you have any questions about this questionnaire, you may call Sucraid*ASSIST*™ at 1-800-705-1962.
Thank you for your time and assistance.