Physician Acknowledgment for the Distribution of SUCRAID®

Patient name (please print):_____

This form is to be filled out by all Physicians prescribing Sucraid for any patient that needs a prescription filled/refilled after July 10, 2015. A separate Acknowledgment Form needs to be completed for each patient prescribed Sucraid.

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 end of this year. As a temporary measure, since Sucraid is in shortage, the FDA has allowed the release of Sucraid lot number A1147. 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.

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:_____

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. Sucraid is the only FDA-approved drug for your condition.

The company that makes Sucraid is going to run out of its regular Sucraid in July and there will not be any regular Sucraid available for several months. 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, A1147. This other kind of Sucraid was made in a place that has not been approved by the FDA. 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 is 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. We hope that the regular Sucraid will be available again before the end of the year.

By signing your name you are saying that you have talked with your doctor and 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 _____

To the Physician/Clinician 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 the pharmacy Accredo at Fax: 866-777-7097.

Sucraid (sacrosidase) Oral Solution Manufacturing Change
Patient Questionnaire - May be Completed by the Patient's Parent or Guardian

TO BE FILLED OUT AFTER TAKING SUCRAID FROM LOT NUMBER A1147 RELEASED DURING SUCRAID SHORTAGE

Patient name_____ **Phone number**_____

1. When did you first start taking Sucraid?
   Month: ____ Year: _____

2. Before you started taking Sucraid, what were your main symptoms? Circle all that apply.
   a) frequent diarrhea
   b) bloating
   c) excessive gassiness
   d) constipation
   e) abdominal cramps or abdominal pain
   f) weight loss
   g) other(s) _____

3. What is your age? _____ months old, OR _____ years old

4. When did you start taking Sucraid from this lot number A1147?
   Month: ____ Year: _____

Since you started taking the Sucraid lot number A1147 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?
   Circle one: 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?
   Circle one: Yes No
   If so, please describe:
   _____

7. Have you noticed a change in the color of this lot of Sucraid?
   Circle one: Yes No
   If so, please describe:
   _____

8. What other changes have you noticed in this lot of Sucraid? Circle all that apply.
   a) Change in taste. Please describe_____
   b) Change in smell. Please describe_____
   c) Change in something else. Please specify and describe_____
   d) No change

9. Have you noticed any other significant symptoms that you believe are related to the new Sucraid? Please describe _____

HIPAA Statement

Authorization to Use and Disclose Protected Health Information ("Authorization"): I authorize my pharmacy, Accredo Health Group, Inc., QOL Medical, LLC, the maker of Sucraid®, 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 the above and other 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 and 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 an Authorized Party may receive compensation; and (5) 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® from Accredo unless I revoke it by sending written notice to the Sucraid® Program Manager at Accredo Health Group, Inc., 1640 Century Center Pkwy., Memphis, TN 38134. If I revoke this authorization, Accredo 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 Accredo Health Group, Inc. at privacy@express-scripts.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 dietary support or peer consultation.

Patient Name (please print) _____ Date_____

Patient Signature (or representative) _____ Relation to patient _____

When you have completed the questionnaire, please send the completed questionnaire by mail (using the postage paid envelope) or by email to info@sucraid.net.

Postage paid envelope to:

QOL Medical, LLC
2015 Patient Questionnaire
3405 Ocean Drive
Vero Beach, Florida 32963

Email to: info@sucraid.net

If you have any questions about this questionnaire, you may call Brandi Rabon, QOL Medical Patient Advocate at 704-692-1634 or brabon@qolmed.com.

Thank you for your time and assistance.