

**Steve Johnson**

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**From:** Greg W. Haffner [GWH@CurranMendoza.com]  
**Sent:** Friday, July 15, 2005 8:47 AM  
**To:** Steve Johnson  
**Subject:** Sure-Way

Steve,

The following are provided to you in response to your letter to me dated July 8, 2005:

<<prior QSR manuals.pdf>> <<contract with Small Business Exchange.pdf>> <<tri fold and post card.pdf>>  
<<Container Spec Sheets.pdf>> <<Certificate of Liability Insurance.pdf>> <<Safety Manual.pdf>> <<OSHA North  
Dakota.pdf>> <<Health Department Violation - ND.pdf>>

Additional documents related to container testing were provided earlier with the 510k file

I still don't have the audited financial statements and tax returns for 03 and 04.

There are no records of distribution of the 1/5/05 QSR manual, or of compliance with the QSR manuals.

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7/15/2005



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Please reply to STEPHEN B. JOHNSON  
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DIRECT: (206) 816-1309

July 8, 2005

Mr. Greg Haffner  
Curran Mendoza  
555 W. Smith Street  
Kent, WA 98035

Re: In re the Application of Sure-Way Systems, Inc./WUTC Docket No. 042089

Dear Greg:

During the deposition on June 24, 2005, we requested and Gary Chilcott agreed to provide us the following additional documents and records:

- Copies of prior versions (prior to 1/5/05) of Sure-Way's QSR Manual, if they can be located;
- Copies of transmittal letters or other records documenting when Sure-Way's most recent QSR Manual (dated 1/5/05) was distributed to Sure-Way's processing plants;
- A copy of Sure-Way's contract with "Small Business Exchange," the company that employs the personnel who work in Sure-Way's operations;
- A copy of Sure-Way's marketing "trifold;"
- Copies of the container test reports generated by Container-Qwinn or other testing company;
- Copies of Sure-Way's audited financial statements and federal income tax returns for 2003 and 2004;
- Evidence that Sure-Way has auto liability insurance;
- Sure-Way's "safety manual," if it exists.

In addition, I advised you at Mr. Chilcott's deposition of our additional requests for:



Greg Haffner  
July 8, 2005  
Page 2

(a) copies of records and documents evidencing Sure-Way's compliance with the requirements of its QSR Manual, including any predecessor version of the QSR Manual (an itemized list of the records and documents we seek is enclosed); and

(b) clarification concerning certain discrepancies noted by our accounting expert in reviewing the Sure-Way financial statements previously provided to us in response to our data requests.

With respect to financial statement issues, we have agreed that our accounting expert will speak directly to Sure-Way's accountant(s) to clarify the apparent discrepancies.

We understand from our prior discussions of this subject that Sure-Way's audited financial statements and federal income tax returns for 2003 and 2004 will not be available until the end of July and that you will provide copies of these materials to us as soon as they are available. In the absence of those materials, we ask that you provide us with a complete copy of Sure-Way's 2002 federal income tax return, since it is apparently the most recent available.

Because the requested materials will be important in preparing Stericycle's prefiled testimony, I request that you provide us the materials and information referenced above as soon as possible and by no later than the end of next week. If that schedule proves to be a problem, please let me know as soon as possible.

Thank you for your cooperation and assistance.

Sincerely,

GARVEY SCHUBERT BARER

By

Stephen B. Johnson

Cc: Greg Trautman  
Mike Philpott

Stericycle requests complete copies of the following records and documents evidencing Sure-Way's compliance with the requirements of its QSR Manual ("QSR"). If the records requested are numerous, and are regularly completed many times each month, please provide one sample of the record for each month within the specified time period.

- All completed "Audit Completion Records" for Quality System reviews evidencing compliance with Management Review requirements for the last three years (QSR 820.20(c))
- All completed "Audit Completion Records" evidencing Quality Audits for the last three years (QSR 820.22) – see QSR Appendix III
- All completed "Audit Worksheets" for the last three years – see QSR Appendix II
- All completed "Quality Manual Training Worksheets" evidencing compliance with Quality Training requirements for the last three years (QSR 820.25) – see QSR Appendix IV
- All completed "Manual Change Record Forms" evidencing changes and modifications to the Design Master Record in the last three years (QSR 820.3(j)) – see QSR Appendix V
- Copies of the "Quality System Record" evidencing changes to the Quality System Manual and the Facility Operating Manual during the last three years (QSR 820.40)
- All documents or other evidence demonstrating that each container manufacturer from whom Sure-Way purchases containers has a Quality System in place (QSR 820.50)
- All documents or other evidence demonstrating that each container has been subjected to a validation test prior to initial use and a challenge test on a quarterly basis thereafter (QSR 820.70(a))
- All completed "Defect Notification Worksheets" for the last three years (QSR 820.80(b)) – see QSR Appendix VI(c)
- All completed "batch worksheets" indicating authorization for containers to be returned to service for the last three years (QSR 820.80(d,e))
- All completed "Customer Complaint Worksheets" for the last three years (QSR 820.100) – see QSR Appendix VII
- All completed "Acceptance Reports" for "reuse" containers for the last three years (QSR p.32)
- All completed "Acceptance Reports" for new containers for the last three years (QSR p.32) – see QSR Appendix VI(a)
- All completed "New Product Defect Notification Acceptance Reports" for the last three years – see QSR Appendix VI(b)

Items identified in Sure-Way Systems, Inc.'s Facility Operations Manual, which is part of the QSR Manual:

- All documents or records demonstrating that any modification of the design of the tipper and washer or the containers is signed off by the CEO and the COO (QSR p.39)

- The complete file history related to the manufacturing of the reusable containers (QSR p.39)
- All completed “container logs” for the last three years (QSR pp.39-40)
- All completed “processing logs” for the last three years (QSR p.40)– see QSR Exhibit 2
- All documents or records evidencing the checking and testing of the tipper, washer, and water as described in Section 6, Equipment and Calibration (QSR p.43)
- The “Design Master Record” (QSR p.44)
- All documents or records demonstrating that all changes to the Quality System Regulations Manual are approved in writing by the Compliance Officer and the CEO (QSR p.45)
- All completed “monthly reports” prepared by the Operations Manager related to discarded and/or defective containers as described in Section 10 (p.49)
- All completed “New Sharps Container Acceptance Checklists” for the last three years – see QSR Exhibit 1
- All completed “Daily Container & Rack Checklists” for the last three years – see QSR Exhibit 3(a)
- All completed “Daily 10 & 17 Gallon Checklists” for the last three years – see QSR Exhibit 3(b)
- All completed “Damaged Container Reports” for the last three years (QSR p.83)

Items identified in Sure-Way Systems, Inc.’s Bloodborne Pathogens Exposure Control Plan, which is part of the QSR Manual:

- All completed “Infectious Exposure Forms” for the last three years – see QSR Appendix B
- All completed “Training recognition/confirmation forms” for the last three years (QSR p.76)