

Dear Judge Caille,

In connection with the telephonic pre-hearing conference scheduled for 1:30 pm today and to facilitate your decision on Mr. Haffner's objections to the subpoenas duces tecum served on his client, I provide the following information with respect to the chronology of discovery in this matter:

1. At the time of the March 3 prehearing conference in this matter, I expressed concern that the time allocated to discovery in this matter was insufficient to allow Stericycle to prepare adequately for the hearing. I suggested at that time that enough time should be allowed for discovery to permit at least two rounds of written discovery (data requests) on the assumption that responses to data requests would be provided approximately 30 days after service, as under the Civil Rules. It is my recollection that you pointed out at that time that the Commission's rules require responses to data requests within 10 days. Accordingly, the discovery period allowed in your March 22 prehearing order substantially reduced the discovery period from what I had suggested.
2. Stericycle served its First Data Requests on Sure-Way on April 1, 2005. After several requests for continuances, which I agreed to, and further delay beyond the agreed deadline(s), Sure-Way served its initial responses to our First Data Requests on April 26, 2005.
3. In a 16-page letter to Mr. Haffner delivered to him on May 12, 2005 (copy attached), I informed Mr. Haffner in exhaustive detail that Sure-Way's initial responses were "so completely superficial and unresponsive as to indicate a level of disregard for the Commission's rules that approaches bad faith." In that letter, I pointed out that Sure-Way had not provided Stericycle copies of manuals, policies and protocols referenced in some of the materials provided in response to Stericycle's Data Request No. 50, including its "Safety Manual."
4. On May 25, 2005, Sure-Way served "Revised Responses" to Stericycle's First Data Requests, providing substantial additional information and copies of many additional documents. In its "revised" response to Data Request No. 50, Sure-Way denied that it had a separate "Safety Manual."
5. On June 1, 2005, Sure-Way served copies of additional documents responsive to Stericycle's First Data Requests.
6. In an email message to Mr. Haffner on June 13, 2005 (copy attached), I informed Mr. Haffner that Sure-Way had "entirely failed to respond to our requests for information concerning the registration of Sure-Way's processing facilities and the listing of its reusable sharps containers with the Food & Drug Administration ("FDA"), including our requests for copies of applications, registrations, notifications, listings or other written communications submitted by Sure-Way to the FDA and all written communications received from the FDA concerning Sure-Way's processing facilities and reusable sharps containers," as requested in Stericycle's Data Requests No. 8, 9 and 10.
7. On June 14, 2005, Mr. Haffner forwarded an email response (copy attached) from Mr. Gary Chilcott, President of Sure-Way, in which Mr. Chilcott stated that "Sure-Way is not required to register its facilities with the FDA. . . . We already provide you with our 510(k) file which has all the information we have." (Emphasis added.)
8. On June 24, 2005, Mr. Gary Chilcott appeared at my office for his deposition. Prior to the start of the deposition, Mr. Chilcott provided me copies of applications submitted by Sure-Way for registration of Sure-Way's facilities and listing of its reusable sharps containers with the FDA, each dated May 24, 2005. When asked in the deposition why these materials had not been provided to Stericycle earlier in response to Stericycle's First Data Requests and why Mr. Chilcott had denied having any further FDA materials in his June 14 email, Mr. Chilcott stated that this was an "oversight."

9. During Gary Chilcott's June 24 deposition, he agreed to provide a variety of additional documents identified during the deposition as relevant to this proceeding. By letter to Mr. Haffner dated July 8, 2005 (copy attached), I confirmed the document requests made during the deposition, including Stericycle's request for Sure-Way's "safety manual" and "copies of records and documents evidencing Sure-Way's compliance with the requirements of its QSR Manual," and attaching a 2-page itemized list of those documents.

10. On Friday, July 15, 2005, one day before the Monday on which Stericycle's prefiled testimony was required to be filed, Mr. Haffner emailed to me additional documents responsive to Stericycle's First Data Requests of April 1, including prior versions of Sure-Way's QSR Manual and Sure-Way's Safety Manual. Mr. Haffner represented in his July 15 email that "There are no records . . . of compliance with the QSR manuals." A copy of this email message is attached.

11. Stericycle served subpoenas duces tecum addressed to Gary Chilcott and Dudley Chilcott on Sure-Way's counsel on August 15, 2005. The categories of documents requested are as follows:

A. Requests No. 1, 2, 3 and 4 request documents evidencing Sure-Way's compliance with the recordkeeping requirements of its QSR Manual. Since Mr. Haffner has already represented that no such documents exist, responding to these requests on the record should involve no burden to Sure-Way.

B. Request No. 5 deals with records required by the FDA's Quality System Regulation, 21 CFR Part 820. These record keeping requirements are the source of the record keeping requirements contained in Sure-Way's QSR Manual. Presumably, if Sure-Way does not have records of compliance with its QSR Manuals, as Mr. Haffner has represented, Sure-Way likewise has no documents to evidence compliance with 21 CFR Part 820 and the burden of responding to this request should be minimal.

C. Request No. 6 requests records required to be kept by Sure-Way's "Employee Handbook," including the "Supervisor's Manual," the "Problem Resolution Procedure" and the "Work Force Drug & Alcohol Testing Act [sic?]" referenced therein. These manuals, policies and procedures were covered by Stericycle's First Data Requests and should have been produced previously.

D. Request No. 8 requests records required to be kept by Sure-Way's "Safety Manual," a copy of which was first provided to Stericycle on July 15, 2005 (after the existence of the "Safety Manual" had been denied by Sure-Way in its "Revised Responses" of May 25). Stericycle was prevented from following up previously on the records requested because of Sure-Way's failure to timely provide Stericycle a copy of the Safety Manual.

E. Requests No. 9 and 10 request Sure-Way's 2003 and 2004 federal income tax returns and audited financial statements which were covered in Stericycle's First Data Requests and which Sure-Way had previously indicated would be available in late July or mid-to late August but which Sure-Way has not yet produced. Sure-Way has repeatedly promised to produce these documents when they are available.

F. Requests No. 11 and 12 request documents related to factual assertions made in Sure-Way's prefiled testimony. Stericycle would be entitled to obtain these documents through a records request during the hearing in any event. See WAC 480-07-400(c)(iv). Stericycle has notified Sure-Way of these requests in advance of the hearing as a courtesy and in an effort to expedite these proceedings.

G. Request No. 7 requests documents required to be kept by Sure-Way under its Montana medical waste operating permit. Stericycle would be entitled to obtain these documents through a records request during the hearing in any event. See WAC 480-07-400(c)(iv). Stericycle has notified Sure-

Way of these requests in advance of the hearing as a courtesy and in an effort to expedite these proceedings.

The Commission's rules provide that "the subpoena, including a subpoena duces tecum" is "available in all adjudicative proceedings." In the context presented by Sure-Way's recalcitrant and inadequate responses to Stericycle's Data Requests, the relevance of the records requested in the subpoenas, the reasonableness of these document requests and the minimal burden imposed on Sure-Way, the Commission should uphold Stericycle's subpoenas and require Sure-Way to comply.

Since we have another prehearing conference in this matter scheduled for Tuesday, August 23, 2005 at 9:30 am in Olympia, I would suggest that we defer extensive argument on these points this afternoon and address this matter on Tuesday.

Respectfully submitted,

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