

**Steve Johnson**

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**From:** Greg W. Haffner [GWH@CurranMendoza.com]  
**Sent:** Tuesday, June 14, 2005 4:43 PM  
**To:** Steve Johnson  
**Subject:** RE: Sure-Way Responses to Stericycle Data Requests

Steve,

Gary Chilcott is on the road this week, but he was able to provide me with some information to respond to your continued inquiries. He will try to provide some limited additional information tomorrow. I will respond to each of your questions below in ***bold blue italics***.

Greg

-----Original Message-----

**From:** Steve Johnson [mailto:SJohnson@gsblaw.com]  
**Sent:** Monday, June 13, 2005 3:11 PM  
**To:** Greg W. Haffner  
**Subject:** Sure-Way Responses to Stericycle Data Requests

Greg,

(1) Sure-Way has 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. See Data Requests No. 8, 9 and 10.

For each Sure-Way processing facility, please provide a copy of Sure-Way's application to the FDA for registration of the facility, if any, and any other written communications to or from the FDA concerning the registration and/or any of Sure-Way's processing facilities. ***Sure-Way is not required to register its facilities with the FDA. See attached email. We will provide copies of the FDA authorizations for the manufacturers of the containers (L&H and Rotonics) those requests will be made tomorrow. I understand Stericycle uses Rotonics so I assume Stericycle doesn't have a problem with them.***

For each Sure-Way reusable sharps container, please provide a copy of Sure-Way's application to the FDA for listing of the sharps container as a medical device, if any, and any communications to or from the FDA concerning the listing and/or Sure-Way's reusable sharps containers. ***We already provided you with our 510(k) file which has all the information we have. If you are looking for information based on the different sizes of the containers, it does not exist, since Sure-Way was only required to register its family of containers based on its largest container. The Rotonics containers are handled the same.***

Sure-Way should have filed annual reports with the FDA for each of its processing facilities, if they were properly registered with the FDA. These annual reports fall within the scope of our requests for written

7/18/2005

communications to the FDA concerning Sure-Way's processing facilities. Please provide copies of all such annual reports and any communications to or from the FDA concerning such annual report(s). ***Sure-Way is not required to register its facilities with the FDA. See attached email.***

The materials provided to us under cover of your letter dated June 1, 2005 deal only with Sure-Way's 510(k) premarket notification filings with the FDA and thus are not responsive at all to our Data Requests No. 8 and 9, which requested information and documents related to Sure-Way's registration of its processing facilities and listing of its sharps containers with the FDA. Similarly, the materials previously provided with your June 1 letter are only partially responsive to Data Request No. 10. ***The 510(k) file is what Sure-Way has. We note that Stericycle only produced copies of its letters of authorization to market in response to our similar data request.***

(2) Sure-Way has failed to respond to our requests that Sure-Way identify each inspection, examination or review of any of Applicant's facilities, vehicles or operations conducted by the FDA or any other governmental agency since 1990 and provide copies of inspection reports, citations, notices of violation or other actions, notices or reports issued by the agency and any correspondence between Applicant and the agency with respect thereto. See Data Request No. 13. ***We may have older versions of the Montana state inspections which we believe say the same as the 2004 version we already provided. We will produce them if we find any and will look for them this week. Sure-Way's California plant was inspected by the FDA in 2000, but no records of the inspection can be found and the plant was sold in 2000. The only vehicle inspections we are aware of are road-side inspections by DOT. Sure-way has no records of those inspections because of the frequency of their occurrence.***

(3) I am still waiting for an explanation as to why Sure-Way's 2003 tax return is "unavailable" and again request that you pursue this issue with your client. In the absence of an adequate explanation for Sure-Way's failure to file a 2003 tax return, we must continue to insist that Sure-Way provide us a copy of its 2003 tax return. ***Sure-Way does not have a 2003 tax return to provide you and will not until approximately late July 2005, when the accountant has told them it will be ready. I will try to get for you an explanation from the accountant.***

Please advise me when we can expect to receive the information and materials identified above. If by tomorrow I do not receive your assurance that these materials will be promptly made available to us, I will ask Judge Caille to schedule a discovery conference to consider the matter.

Thank you for your assistance.

Steve



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