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PHARMACEUTICAL LABORATORIES, LTD.

Orig: DD/EF
DIB
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AOC

August 22, 2008

Ms. Joanne Givens, District Director
Detroit District Office
Food and Drug Administration
300 River Place, Suite 5900
Detroit, Michigan 48207

Re: Bi-weekly update.

Dear Ms. Givens,

This letter represents Caraco's third [redacted] update of the remaining compliance projects associated with our May 2008 FDA inspection. Although there were no action items due this period, we remain on target to complete the two final items.

In the attached Action Plan, the two remaining projects (GMP Training by [redacted]) are highlighted in bold letters. The GMP training sessions are scheduled for September 15 through 19 and September 29 through October 3, 2008. This is a little later than anticipated primarily due to scheduling conflicts with [redacted] trainer and the devotion of additional time to the job specific training portion of the GMP training sessions. Furthermore, the hands-on training for our quality auditing group with [redacted] is scheduled for the subsequent week, October 6 through 10, 2008. This training will assist the auditors that now support the manufacturing process areas, providing consistent auditing techniques to uncover non-compliance or verify that we are in a constant state of control and compliance. (b)(4)

Our bar coding project as part of the process flow to dispensing remains ahead of schedule with the completion of the preliminary testing of the system hardware and software. We have purchase orders submitted for hand scanners and ruggedized flat screen personal computers that are being wall mounted next week in the dispensing area. Final testing will begin once the installation is completed. Standard operating procedures are being written and reviewed which will also be complete by the end of next week. We should also note that we are taking the bar code process that is being implemented in dispensing one step further by developing [redacted] capabilities to be used in the overall operation. I am currently involved in mapping out where the [redacted] technology is most applicable within our internal supply chain. This is a natural progression that the industry is working towards as part of product pedigree traceability in the distribution supply chain. We believe that it will offer a myriad of solutions within our overall operation. (b)(4)

The formal Compression Operator and Supervisor training continues to occur each month, with training sessions with the compression machine manufacturers scheduled each month throughout the remainder of 2008. In addition, Caraco sent [redacted] designated "[redacted]" to the manufacturer's facilities this week for training in advanced methods in machine maintenance and operation. A majority of our incidents are in compression as we noted earlier and the other area relative to compression is coating. We believe this type of training will considerably lower the incident rate in these areas. (b)(4)

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As previously committed, I will continue to provide you with further updates on Caraco's progress in the next [redacted] report. I have also included the current timeline for our expansion of our facility at 1150 Elijah McCoy. As stated in my previous update letter, this is a rolling plan based on the completion of our construction. The expansion project remains on schedule. (b)(4)

As always, if you have any questions or comments, please do not hesitate to contact me at [redacted] (b)(6)

Sincerely,

Daniel Movens, CEO
Caraco Pharmaceutical Laboratories, Ltd.

Attachments: Caraco Action Plan, dated August 22, 2008; Caraco Plant Expansion Timeline for 1150 Elijah McCoy