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PHARMACEUTICAL LABORATORIES, LTD.

Orig: DD/EF w/attachments
cc: DCB w/xc attachments
cc: DIB
ljk 8/11/08

August 8, 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 second [redacted] update of the remaining compliance projects associated with our May 2008 FDA inspection. We have completed four action items since our last correspondence and have two remaining. (b)(4)

In accordance with the attached Action Plan, Caraco continues to complete all action items indicated. The projects that have been completed and implemented are highlighted in the Action Plan in bold letters. During the week of August 4, 2008 [redacted] performed in-house training on the investigative process to [redacted] personnel involved in investigations at our facilities. This training involved the practical use of statistical tools for risk analysis, root cause determination, and the identification of permanent corrective actions. This interactive training was engaging and we anticipate additional improvements to our incident and complaint investigation process in the coming weeks as a result of this training. (b)(4)

[redacted] will be performing an additional training session with our Quality Audit group in order to provide hands-on training on how to conduct more systematic and effective internal audits of our operations. We plan to start training the week of September 8, 2008. We had a few additional hires that we thought should also be included in this quality assurance training program, the last of which starts August 27, 2008.

In addition, Caraco has coordinated in-house training at our facility with the manufactures of our compression machines for the past [redacted] months. As we previously mentioned, we have been moving towards integrating automated compression machines over this past year and found that the transition to these complex machines was contributing to an increase in incidents. [redacted] from [redacted] (automatic compression) and [redacted] (for the remaining manual machines) have met with Compression Supervisors and Operators each month to teach improved set-up procedures and overall operation methodologies. They have also discussed the inner workings of the machines which will provide a better understanding to troubleshoot problems should they occur for these presses. Similar training has been scheduled for this month. Super users are also being identified so that we are not reliant on the manufacturer for this type of training in the future. (b)(4)

The remaining two items on the Action Plan are tracking for successful completion. Our supplemental GMP training with [redacted] has been scheduled. Furthermore, we have begun system trials for new bar coding equipment and process within the Dispensing Department. Basically the bar code system is functional and raw materials that are bar coded can be read with a scanner for correct (b)(4)

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identification. We are currently working on going wireless in the dispensing area since it is not practical being a hard wired application. Again this is in test and will have to be reviewed and approved by Quality along with our internal financial auditor. We are pleased that it is functional in its hardwired stage and plan to roll it out in dispensing first, once we move to wireless which appears to be ahead of schedule.

Further we redesigned our floor plan for improved process flow of product in dispensing. In that project we were able to allocate more space for staging for both incoming material as well as outgoing material. Keep in mind that dispensing will be moving to the expansion area of our new facility on Elijah McCoy Drive, once our construction is completed.

As previously committed, I will continue to provide you with further updates on Caraco's progress in the next bi-weekly report. I have also included our tentative timeline for our expansion of our facility at 1150 Elijah McCoy. This is a rolling plan based on the completion of our construction. It appears that we are on time at this point and the plan seems achievable. This project will go a long way to minimize material handling, improve process flow and increase capacity. I am personally happy that senior management will be in the same building as a majority of our operation. Though it took three years for the local approval process we are finally seeing the outcome of our efforts.

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 8, 2008; Caraco Plant Expansion Timeline for 1150 Elijah McCoy