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CARACO
PHARMACEUTICAL LABORATORIES, LTD.

September 5, 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 fourth [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. (b)(4)

In the attached Action Plan, the two remaining projects (GMP Training by [redacted]) are highlighted in bold letters and remain on target for completion. The wall-mounted computers for the bar code scanning operation in dispensing are scheduled to be installed once they are received from the vendor this week. Final testing of the system will begin once the installation is complete. (b)(4)

At the beginning of the FDA Inspection, Caraco was completing a departmental change involving the technical personnel responsible for the closure of incidents and corrective/preventative actions. This change included the creation of Caraco's Quality Engineering Department within the Quality group. This new department made significant improvements to the Investigation process, such as the following:

- The number of personnel responsible for incident investigations tripled from [redacted] people to improve the quality and timeliness of investigation reports. (b)(4)
- The department has undergone [redacted] training sessions on investigative techniques and root-cause analyses. Quality management is scheduled to attend a third, off-site session on permanent Corrective Actions at the end of this month.
- The Quality Engineers manage the investigation from the onset of the incident, utilizing a more detailed incident tracking form.
- The process has been enhanced to perform more detailed risk assessment and root cause analysis [redacted] (b)(4)
- The closure of investigations is being tracked through an electronic notification process linked to our [redacted] mail system.
- Occurrences that can be resolved immediately can now utilize the "[redacted]" process which documents the item within the batch manufacturing record.

These changes have already proven to add value to our quality system, with a dramatic reduction of outstanding incidents, improved incident tracking, and more thorough investigation reports.

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As you may be aware, we have integrated staff that has had experience at other pharmaceutical companies in both the generic and brand sectors. Many of these people bring best practices that we deem important to implement. One such practice are the [redacted]. Our compression department has completed the initial validation of the first [redacted], which was completed during the week of August 25, 2008. Following the successful validation, we have received an additional nine metal detectors. Our long-term plan is to add metal detection devices to each compression machine in our facility as an additional quality safeguard. This project involves the eventual purchase, installation and validation of over [redacted] units during the next [redacted] months. (b)(4)

In addition, Caraco's compression department recently purchased a compression tooling inspection and management system. This system utilizes laser technology to inspect the length, diameter and concavity of compression tools to determine the variability and wear on each tool to ensure consistent compression operations. It also provides better control of our compression tool inventory by monitoring each tool in a set for pitting, fractures or any other anomalies, and adjusting the set inventory levels when tools fail to meet the pre-established specifications. We believe this additional control will assist us in maintaining the integrity of our tooling that is being utilized which in turn will lower our incidents related to compression.

Lastly we have had supplemental training in the set up process of our coating machines and have provided guidance on where the personnel errors have been occurring that had caused the incident rate to increase over time. We have had supervisors review the issues caused by their staff and have them physically reviewing the actual impact on the next step process area. This process has been very insightful for those personnel. In order to further change the paradigm we are having each process operator trained in the "next step" process so they can see what impact they have on the next process step team. This will allow previous process operator insight in how any error would impact the next process step and the overall product quality.

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 September 6, 2008; Caraco Plant Expansion Timeline for 1150 Elijah McCoy