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PHARMACEUTICAL LABORATORIES, LTD.

Orig: DCB w/attachments
cc: DD
cc: DIB
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October 03, 2008

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

Re: Caraco compliance update

Dear Ms. Givens,

This letter represents Caraco's sixth update of the remaining compliance projects associated with our May 2008 FDA inspection. The last two remaining items on Caraco's Action Plan remain scheduled with [redacted] The second half of the additional cGMP training is scheduled for the week of October 6, 2008 and the training for the Quality Assurance Auditors is scheduled for the week of October 13, 2008. During the week of September 22, our Associate Director of Quality Assurance and Manager of Quality Engineering attended an off-site training class on root cause analysis and corrective & preventative actions, provided by [redacted] This [redacted] course focused on providing additional tools utilized for reliable root cause analysis, as well as case study evaluations relative to CAPA programs. (b)(4)

Caraco remains on schedule for the completion of the expansion of our facility at 1150 Elijah McCoy. We expect to have a *Certificate of Occupancy* from the City Inspector in mid-November. In general, the new facility will include the following:

- Movement of Raw Material Receipt and Storage from the Holden facility to 1150 Elijah McCoy
- Movement of Dispensing Operations from the Holden facility to 1150 Elijah McCoy
- Movement of Company Administration, including myself, from the New Center One building to 1150 Elijah McCoy.
- [redacted] Additional Granulation/Blending Suites
- [redacted] Additional Compression Suites
- A[redacted] Training Center (b)(4)

I have included a copy of the 1150 Elijah McCoy Plant Expansion Timeline with this update for your review. Note that the project has remained on schedule for the past several months.

The new Quality Assurance Auditor function has been implemented in September 2008. This group is responsible for the on-line review of batch documentation at each stage of the production process. In addition, the QA Auditors provide real-time support to Operations personnel relative to cGMP and incident resolution. We are pleased with the systems and personnel we have implemented to monitor and investigate incidents. The company has seen a dramatic reduction in the amount of incidents as a result of this and many other process improvements implemented. The bar code system in place in dispensing is working very well and we expect that we will implement the [redacted] tracking along with integration of our dispensing scales to our [redacted] once the programming is completed. (b)(4)

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As previously committed, I will continue to provide you with a final update on Caraco's progress in the next report. The next report will be sent on October 24, 2008 which will mark our completion of all activities listed in our Action Plan. I have also included the current timeline for the expansion of our facility at 1150 Elijah McCoy.

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 October 10, 2008
Caraco Plant Expansion Timeline for 1150 Elijah McCoy