CARACO
PHARMACEUTICAL LABORATORIES, LTD.

Orig: DD/EF w/attachment
cc: DCB w/xc attachment
cc: DIB
ljk 7/28/08

July 25, 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 following Caraco's response letter dated July 10, 2008.

Dear Ms. Givens,

As indicated in the cover letter to Caraco's FDA Form 483 response, I am providing you this [redacted] update of the remaining compliance projects associated with the May 2008 FDA inspection. (b)(4)

In accordance with the attached Action Plan, Caraco has completed all action items as of the date provided in our initial response letter. The projects that have been completed and implemented are highlighted in the Action Plan in bold letters. We have re-evaluated our timeline on GMP training by [redacted] and have determined that the supplemental, job-specific, GMP training will take an additional [redacted] days to thoroughly complete. All employees receive GMP training upon hire and re-training is done at least annually. Investigative Technique training was moved from being final on July 31, 2008 to August 8, 2008. These changes were made due to scheduling conflicts with the appropriate personnel at [redacted] Internal training on investigative root cause analysis will be completed before July 31, 2008. (b)(4)

Caraco remains focused on the completion of this Action Plan as proposed. We have fortified our Quality staff by moving qualified Caraco personnel to the Quality Auditor team. We have also hired a Supervisor of the Quality Assurance Auditors. Additionally, we have received applications and have offers out to potential candidates who will continue to improve compliance, initiate preventative actions and implement corrective actions. As you would expect, we are continually working through our corrective and preventative action plans. As I have conveyed previously we are looking at global improvements and are taking a holistic approach in our improvement plan. We have dedicated Quality Assurance Auditors to specific GMP areas, such as dispensing and the various manufacturing areas. In addition, our manufacturing supervisory staff is being supplemented in all areas as needed.

I appreciate your time to discuss Caraco's commitment to quality and our efforts to improve compliance with me last week. I will continue to provide you with further updates on Caraco's progress in the next [redacted] (b)(4)
[redacted] report. 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.

Attachment: Caraco Action Plan, dated July 25, 2008