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October 24, 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 seventh and final update of the remaining compliance projects associated with our May 2008 FDA inspection. Almost [redacted] people have undergone supplemental cGMP training. There is still additional training required that will conclude November 4-6, 2008. The trainer from [redacted] had become ill mid-week during training and asked to reschedule. As planned last week, specific internal auditing training was conducted by [redacted] for [redacted] Quality personnel. This training was broken into four full one-day sessions and entailed the entire manufacturing process area. Groups of [redacted] began in the receiving area and inspected/audited the entire manufacturing process in the course of each day, learning from an ex-FDA Inspector on audit techniques. Actual observations were documented during the audit training to ensure that corrective actions are created and tracked to completion. (b)(4)

With the completion of the auditor training last week, Caraco Quality Assurance will undergo a change in the manner that production and records are monitored. On November 3, 2008, Quality Assurance personnel from three separate groups, including Batch Record Review, In-Process QA, and Quality Auditing will be combined into one single group responsible for all QA functions relative to batch processing and release. The QA group will monitor and mentor in real-time. This will allow interaction in manufacturing with the long-term benefit of eliminating any process errors and improving documentation errors. It will eliminate errors and incidents previously found after the production process is completed. This improvement provides for more than double the amount of Quality Assurance personnel on the production floor at any given time [redacted] (b)(4)

We are making continual improvements as we should and have seen many benefits out of those efforts. For example, we have seen that the incident rate has dropped by [redacted]. The number of incidents caused by personnel error has also dramatically reduced by over [redacted] during the last three months. We believe this is due to various action steps we have taken including but not limited to improved management, supplemental cGMP training of employees and corrective and preventative action plans. The root cause analysis training of Caraco's investigative team has addressed what could have been future incidents. Many additional process improvements remain active in all functional areas at Caraco to reduce the number of incidents and improve compliance even further. (b)(4)

Caraco committed to hire an additional quality assurance manager among the various personnel that were intended to supplement our team. During this long and difficult process we found a senior manager who exceeded our initial qualifications. This person has over [redacted] years of experience in pharmaceutical quality assurance management and will be a real asset in our goals for continuous (b)(4)

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improvement. This person will work on special projects designed to improve our systems throughout the entire global process.

Additionally Caraco has had in place an open door policy on any non-compliance issue that expects that any employee at any level has the right, if not the obligation, to report any non-compliance issues ranging from cGMP issues to the Sarbanes Oxley requirements of a public company. All employees have complete access to all levels of management to report any issues that they deem reportable. As our staff has grown it appears there could be a gap in what management has reported to it under its open door policy. Effective no later than November 1, 2008 we will have initiated our [redacted] (b)(4) ([redacted]) hotline. This hotline information will be posted in each of our facilities for our staff to call and report any non-compliance issues. A letter is being finalized to go out in our next payroll to explain the obligation of each of our employees to report any unethical behavior of any kind.

Caraco remains relatively 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-to-late November. Potential move in for administration is the first week of December. We are excited to be in the same facility as our manufacturing process. The completion will allow us to begin the transition from the New Center One offices and the 1200 Holden facility into one primary production facility. As in previous updates, I have included a copy of the 1150 Elijah McCoy Plant Expansion Timeline with this update for your review. If you or anyone else from your office would like to visit the facility before it opens please let me know. When the facility expansion is completed, we hope that you, Judy Putz, Patsy Domingo, Rebecca Dombrowski, Azza Talaat and others from your office will join us our ribbon cutting ceremony.

Since the activities listed in the attached Action Plan are substantially complete (with the exception of the completion of the rescheduled supplemental cGMP training in the first week of November), this will be Caraco's final compliance update of our response. It was our intention to be as comprehensive as possible in all our correspondence. If you feel that I may have overlooked any matter please let me know. Hopefully, through our correspondence, you have seen our commitment to compliance and a sense of urgency that will continue. I thank you for your time invested in the inspection process and look forward to our next inspection. 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 24, 2008
Caraco Plant Expansion Timeline for 1150 Elijah McCoy