CARACO
PHARMACEUTICAL LABORATORIES, LTD

Orig: JAP w/Manual
cc: DD/EF
cc: DCB
cc: DIB
ljk 7/11/08

July 10, 2008

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

Re: FDA 483 issued June 11, 2008 to Caraco Pharmaceutical Laboratories, Ltd.

Dear Ms. Givens,

Caraco Pharmaceutical Laboratories, Ltd. (Caraco) has carefully reviewed the FDA Form 483 observations presented by the investigators. We appreciate the professional manner in which the investigation was conducted. As we have done previously, we commit to provide you with regular updates on our continuing improvements and corrective actions. We will also include updates on our expansion process of our [redacted] manufacturing facility adjacent to our current facility, which is due to be completed in October 2008. We have a rolling plan through February 2009 for transitioning certain manufacturing functions to that part of our building which will be merely a large addition to our current facility. (b)(4)

We have invested significantly in our infrastructure in order to improve quality and productivity. We have invested in people, equipment and facilities in order to provide an improved outcome. As you know last year we purchased and retrofitted our packaging plant that we acquired from our former third party packager. We replaced the manual packaging lines and moved to automated lines that require less human intervention. Also last year at our manufacturing plant in Detroit we started a program to transition to [redacted] compression machines. To date we have installed and validated [redacted] compression machines with new [redacted] and we have [redacted] more ordered that will be validated over the next [redacted] months.. We have also expended considerable time and resources in our Quality Control Laboratories. We are proud of what we have accomplished in this department and I'm sure that the investigators can attest to the major improvements made in this area (b)(4)

In conjunction with the growth in facilities and equipment we have experienced growth in our workforce. We now employ approximately [redacted] people. In order to improve the quality of our workforce, we have partnered with the [redacted] in developing a training program for our pharmaceutical operators. We have provided various pieces of equipment and [redacted] has developed a training program which covers aspects of machine operation, training in Good Manufacturing Practices, as well as Safety Training. As of April 2008 this program graduated [redacted] of employees and as of July 1, 2008 this program has graduated [redacted] groups of employees. (b)(4)

As mentioned in our previous letter, prior to this inspection we expanded our manufacturing management and supervisory staff as well as re-positioned the responsibility of certain departments to provide enhanced oversight and accountability

We hope that Caraco's commitment to continuous improvement was evidenced during this recent inspection. I have also met with all employees personally in group meetings over the last two weeks to discuss our shortfalls and our accomplishments. We focused specifically on cGMP compliance and the level of commitment required as a Caraco employee in highly regulated business. This was a global discussion to supplement our job specific training and our regular cGMP training. I also explained that

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we have hired an outside firm for additional training and self audits to ensure that we stay on track. I spoke of my of being highly available and visible for any issue that will improve our performance and reconfirmed our commitment to quality as an organization. We spoke of accountability to each other to make a difference now and for the foreseeable future.

As specified during the closeout meeting held on June 11, 2008, we are providing this written response to the observations presented by the investigators.

We understand that the observations are not all inclusive and could represent broader issues. To that end we have reviewed the observations from a global view. Actions taken in response to the observations apply not only to the specific observations, but to the systems they represent.

As committed previously we have continued to undergo annual external audits by outside consultants. The most recent audits prior to this inspection were conducted in August of 2007. As noted in my previous letter upon receiving the observations on June 11, 2008, we immediately contacted [redacted] (b)(4) [redacted] for their assistance in the preparation of our response plan but more importantly to conduct additional training in cGMPs where needed and training on our investigative techniques. We are also arranging for additional external audits.

In the attached response, we have followed a format of re-stating the written observation in bold and followed each with Caraco's response. We have included copies of all relevant procedures and supporting documents.

We request that a copy of our Response to the FDA 483 be included with each FOI request for this FDA 483 and EIR.

Caraco is strongly committed to supplying the highest quality generic pharmaceuticals in compliance with all Federal, State, and Local regulations. If the FDA requires any additional information or explanations, please do not hesitate to contact us. We will proactively supply you with a [redacted] (b)(4) update for any ongoing or remaining Corrective Action Plans. Also provided is a summary time line of commitments for easy reference. We will be happy to meet with you to discuss any concerns or questions you may have concerning our response or our Plan.

Sincerely,

Daniel Movens, CEO
Caraco Pharmaceutical Laboratories, Ltd.