



Orig: *my* DD/EFW/attachments
cc: DCB w/xc attachments
cc: DIB
ljk 9/19/08

September 19, 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 fifth [REDACTED] update of the remaining compliance projects associated with our May 2008 FDA inspection. Following the last FDA update, there were two remaining open items. The first was the completion of cGMP training for Caraco employees by [REDACTED] (b)(4). The second was the addition of a barcode verification system within the dispensing area. We have added another item to be tracked into the Action Plan. We have scheduled additional training with [REDACTED] for the Quality Assurance Auditors to provide auditing training to Caraco personnel. This training is scheduled for completion during the week of October 13, 2008.

During the week of September 15, 2008, [REDACTED] began providing job specific training cGMP training to each Caraco employee involved in cGMP operations as a supplement to our own training. This training is divided into small groups of people from similar functional areas, so the training would be focused on examples pertaining specifically to each function. The training is being performed by a senior member of [REDACTED] who not only has extensive experience as a regulatory consultant, but was also with the FDA Office of Compliance for over 10 years. The real-life examples used during training, which are based from the [REDACTED] that she has audited, have provided additional insight to Caraco employees on the importance of cGMP compliance. There have been [REDACTED] training sessions performed this week. The remaining training sessions, which includes additional production and executive management, is scheduled for the week of October 6, 2008 as indicated in the attached Caraco Action Plan and [REDACTED] cGMP Training Schedule. (b)(4)

Caraco has completed the week long pilot evaluation of the barcode scanning project in the dispensing department this week as planned. The objective of this system is to scan the raw material source containers as they are brought into dispensing area in order to eliminate any possibility of error. At the time of raw material receipt at Caraco, quarantine labels are printed with a barcode by our [REDACTED] system and are affixed onto each container by Materials Management employees. Each dispensing room now has a computer terminal and barcode scanner located within the room. Prior to dispensing a particular batch, the associated work order issuance is retrieved from the [REDACTED] system via the computer within that dispensing room. The [REDACTED] has assigned a specific receiving number for the raw material used for each batch issued within the system. When a batch is dispensed, the barcode system verifies that the material being dispensed matches both the exact material and the receiving number of that material identified as being allocated for that specific batch within the [REDACTED]. If the wrong material is brought into the room, the system would alert the operator at that time. The applicable dispensing procedures associated with this system, as well as the general dispensing procedure describing the use of barcode verification are under final review and will be effective by September 22, 2008. We also expect that (b)(4)



additional functionality will be launched in the next few weeks that will incorporate the [REDACTED] directly in our [REDACTED]. If the weight is accurate as dispensed the system will approve. If weight is off it will alert the operator and will not allow to confirm the transaction. (b)(4)

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,

A handwritten signature in black ink, appearing to read "Daniel Movens", is written over a horizontal line.

Daniel Movens, CEO
Caraco Pharmaceutical Laboratories, Ltd.

Attachments: (b)(4)
Caraco Action Plan, dated September 19, 2008
[REDACTED] cGMP Training Schedule
Caraco Plant Expansion Timeline for 1150 Elijah McCoy