MedPointe pharmaceuticals

October 29, 2003



Charles E. Matoesian
Division of Legal Counsel
Illinois Environmental Protection Agency
1021 North Grand Avenue East
PO Box 19276
Springfield, Illinois 62794

Re: Wallace v. IEPA, PCB 02-207 (Air Variance)

Dear Mr. Matoesian,

As per condition 3.h. of the Order granting a variance in the above referenced matter, MedPointe Healthcare, Inc. is submitting this letter as a progress report for the period from April 1, 2003 through September 30, 2003. As noted previously, the Wallace Pharmaceuticals' name has been changed to MedPointe Pharmaceuticals.

According to the Order, MedPointe is required to report on the progress of the development of a suitable alternative to the usage of ethanol in the affected processes. During the above referenced period, we were installing new air handling equipment in the tablet production area, and the tablet production area was idle from March through early June. As a result, we outsourced the development and production of two new tablet products that were recently introduced to the market. In the event that manufacture of these products is transferred back to Decatur in the future, we are pleased to report that their direct-compression manufacturing processes do not involve the use of ethanol. These research efforts should satisfy both conditions 3.a. and 3.b. of the Order, in that the bench-top, pilot, and commercial scale processes were successful for these products, and do not utilize VOM solvents.

As we reported last April, a dry granulation process which uses no ethanol is in use for Tussi 12-D Tablets, a new product launched by MedPointe in 2002. We expect to continue further evaluation of the dry granulation processes and substitute, where possible, for the ethanol-based wet granulation process.

We continue our research efforts with emphasis being placed on non-VOM products and processes for our future product development. These efforts should not only minimize our VOM emissions but quite possibly keep them well within our pre-variance levels. In light of the items mentioned above, it is likely that add-on control technology may not be necessary to achieve compliance with our pre-variance limits of 12.5 tons per year.

At this writing, we expect our VOM emissions to be well below the allowable variance limit of 25 tons per year.

I trust this brief letter report satisfies the Order requirement for a progress report. If any additional information is required please advise.

Sincerely,

William J. Taraszewski, Ph.D.
Director, Pharmaceutical Production

cc:
Dorothy Gunn, Clerk
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