MDS says FDA approves drug-study review plan

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MDS Inc.; MDS.TO: will move ahead with its plan for a data review of generic drug studies dating back to 2000 after getting a go-ahead from U.S. regulators, the Canadian health services company said on Monday.

Questionable data from MDS Pharma Services' bioequivalence studies have put it in the doghouse with U.S. regulators, who issued a scathing letter last year detailing a number of concerns. Criticism included MDS's failure to conduct a thorough and systematic evaluation of contamination that occurred during a study sample analysis.

MDS Pharma said it met with the U.S. Food and Drug Administration on Feb. 2 to discuss its plan to review generic drug studies conducted at the company's Montreal facility between 2000 and 2004.

On Monday, MDS said the agency indicated that it agreed with the overall approach of the review.

The studies will be reviewed in order of priority, based on specific criteria described in the plan, following appropriate review processes and quality assurance checks, MDS said in a statement.

It added that the need for subsequent reviews, analysis and corrective action will be determined as the results of the individual reviews are obtained.

The review process is expected to help offset worries about company's regulatory woes.

"People who have been giving pharma business to MDS will have second thoughts about the quality of work that is being done at MDS Pharma," said **Neeraj Monga**, vice-president of **Veritas Investment Research**.

"It's already a setback for the company, the stock is down 20 percent and it will make it difficult to either gain credibility from current customers or gain new customers."

MDS said about 30 people are working on the review project though it would not disclose how much the process will cost.

"We will spend as much as we need to spend to get the process done," said Mike Nethercott, an MDS Pharma spokesman.

MDS has hired independent adviser Lachman Consultant Services to assist in the review plan development. Lachman will also be involved in overseeing the execution of the review plan by MDS Pharma.

MDS said it could not forecast when the process would be completed.

"Until we have executed the review on a minimal number of studies, we will have an idea of how long it will take and then we will lay out a timetable," said Jim McClurg, chief scientific officer with MDS Pharma.

Shares of MDS rose 12 Canadian cents to C$16.70 on the Toronto Stock Exchange on Monday.

($1=$1.26 Canadian)