

Glaxo to pay \$750 million in adulterated drugs case

By Toni Clarke

Reuters

BOSTON (Reuters) – GlaxoSmithKline Plc has agreed to pay \$750 million and plead guilty to manufacturing and distributing adulterated drugs from a now closed plant in Puerto Rico, the U.S. Justice Department said on Tuesday.

The company had said in July it reached an agreement in principle relating to quality problems at its SB Pharmco Puerto Rico Inc's plant and would pay about \$750 million to resolve the allegations.

Of the \$750 million, Glaxo will pay \$600 million to settle allegations that, because the drugs were adulterated, false claims for reimbursement were submitted to government healthcare programs.

The drugs -- the anti-nausea medicine Kytril, skin ointment Bactroban, anti-depressant Paxil CR and diabetes drug Avandamet -- were made at the plant between 2001 and 2005.

The company was accused of failing to ensure the drugs were properly manufactured at the plant and thus effective, according to the Justice Department.

Under the plea agreement, SB Pharmco Puerto Rico will plead guilty to a felony of releasing adulterated medicines and pay a \$150 million criminal fine that includes forfeiture of \$10 million in assets.

Asked during a news conference if the actions by the company were intentional, Carmen Ortiz, the U.S. Attorney for Massachusetts, said that was the government's contention.

"They received warning letters from the FDA and yet they went ignored," she told reporters. Ortiz also said the investigation into individuals was "ongoing."

A whistleblower who filed a lawsuit under the U.S. False Claims Act will receive about \$96 million from the federal share of the settlement, the Justice Department said.

A federal judge must approve the plea agreement.

Glaxo expressed regret that its factory did not operate within the necessary standards and practices.

"GSK worked hard to resolve fully the manufacturing issues at the Cidra facility prior to its closure in 2009 and we are committed to continuous improvement in our manufacturing processes," PD Villarreal, the company's head of global litigation, said in a statement.

Villarreal said the plant was closed because of declining demand for the medicines made there, and that the company no longer owned the facility.