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FDA: Bausch & Lomb Failed on Reporting

FDA letter: Bausch & Lomb failed on reporting fungal eye infections

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WASHINGTON, Nov. 6, 2006

(AP) Bausch & Lomb Inc. failed to formally report nearly three dozen foreign cases of fungal eye infections later linked to one of its contact lens solutions, according to a federal warning letter.

Bausch & Lomb didn't report the 35 serious injury reports by April 7, as required by law, after Singapore health officials had alerted the Rochester, N.Y. company, the Food and Drug Administration said in the letter. The reporting failure occurred after the company had suspended sales of its ReNu with MoistureLoc solution in Singapore.

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It also came after the FDA had begun an investigation of the Greenville, S.C. manufacturing plant where Bausch & Lomb made the now-withdrawn MoistureLoc solution.

Bausch suspended sales of MoistureLoc in Singapore and Hong Kong in February and U.S. sales in April. It initiated a global recall in May. The company later acknowledged the brand of solution was the potential "root cause" of increased risk of the fungal infection, called Fusarium keratitis.

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Ultimately, health official reported several hundred cases of Fusarium keratitis in parts of Asia and the United States.

The FDA warning letter refers in part to the inadequacy of a previous company response to FDA concerns about its reporting of the Singapore cases.

"Your response states that this information did not reasonably suggest that the ReNu with MoistureLoc multi-purpose solution device caused or contributed to the Fusarium infections. FDA disagrees. This information suggested that your ReNu product may have caused or contributed to the event," the letter reads in part.

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In a statement, Bausch said it has completed more than two-thirds of the corrective actions it pledged in response to the FDA's concerns. The issues stem from the March-to-May inspections of the Greenville, S.C. plant. Bausch said it should be ready for a reinspection before March 31.

The 11-page letter, redacted in parts, largely details previously disclosed manufacturing problems at the plant. The FDA said it found no problems at the plant with any other company products.

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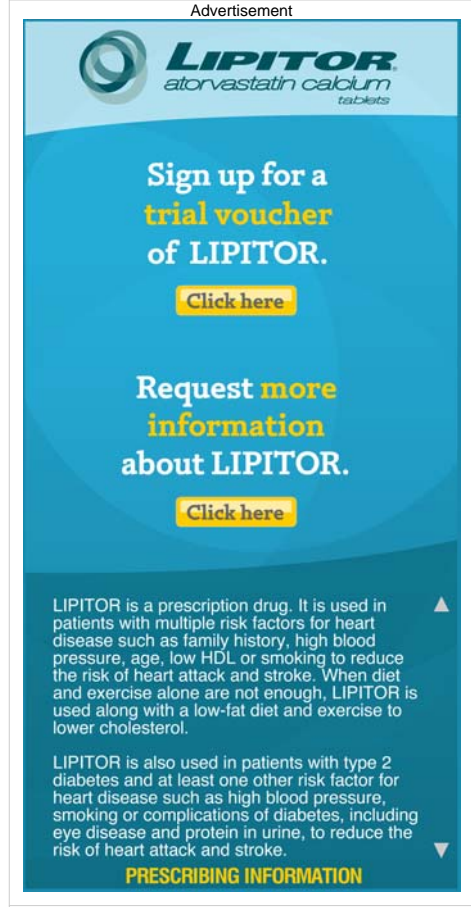
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