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FDA says Roche representative violated marketing rules

Thu Sep 5, 5:44 PM ET

WASHINGTON - The Food and Drug Administration ( ) said in a letter to Roche AG that a company representative violated advertising rules by downplaying the psychological side-effects cited on the label of the company's acne drug, Accutane, at a drug industry meeting.

Switzerland-based Roche said Thursday that the company has since reinforced the need for a balanced presentation of risks and benefits with its sales staff.

The notice of violation letter was posted on the agency's Web site Wednesday.

The letter indicated the Roche representative violated FDA advertising rules by providing misleading information and said Roche should immediately stop similar activities.

However, it wasn't one of the agency's more severe "warning letters," which outline what sanctions the agency might hand down if corrections aren't made.

The company said the FDA told Roche its efforts to correct the problem were satisfactory and the matter has been closed.

According to the FDA letter, two agency reviewers visited Roche's booth at the American Pharmaceutical Association's annual meeting earlier this year and asked a Roche representative if Accutane's label carried a psychosis warning.

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The letter said the Roche representative responded: "We don't feel it's an issue" and "News has hyped it up."

Accutane's label warns the drug may cause depression, psychosis and on rare occasions, suicide. The company has been named in several suits claiming Accutane played a role in suicides, some of which have been dismissed.

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