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USFDA's labeling proposal to increase exposure to lawsuits, says DRL in SEC filing

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Hyderabad, June 27: The new labeling rule, proposed by the US Food and Drug Administration (USFDA), is bound to increase comapnies' potential exposure to lawsuits relating to product safety and warnings on labels, Dr Reddy's Laboratories (DRL) said in a filing with the SEC. The proposed rule aims to bring down safety-related risks, which has been an issue in the regulated markets.

In its submission of Form 20F to SEC, the company said, "If the USFDA's proposed new rule is adopted, it may increase our potential exposure to lawsuits relating to product safety, side effects and warnings on labels. This new potential exposure to lawsuits may also increase the risk that, in the future, we may not be able to obtain the type and amount of coverage we desire at an acceptable price and self-insurance may become the sole commercially reasonable means available for managing the product liability risks of our business."

On November 13, 2013, the USFDA proposed a new labeling rule, which the agency believes will speed up the dissemination of new safety information about generic drugs. Under the proposal, generic drug manufacturers would be able to independently update product labeling.

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