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DRL under US scanner for packaging violations

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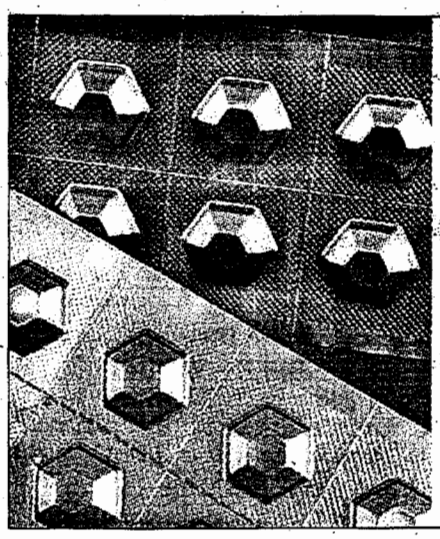
Hyderabad, Aug 20: Dr Reddy's Laboratories has come under the scanner of the US Department of Justice for alleged violations of some provisions of the Consumer Product Safety Act, involving child-resistant packaging regulations. However, the company has denied the Consumer Product Safety Commission's (CPSC's) allegations.

In a filing with the US Securities and Exchange Commission (SEC), the company said that the issue was related to compliance with requirements of special packaging for child-resistant blister packs for six products sold by the company in the US from 2002 through 2011. The company listed out many contingencies in its Form 6K, including litigations on Norfloxacin, Nexium and Zometa, among others.

"The company disagrees with the CPSC's allegations and is engaged in discussions with the CPSC regarding its compliance with the regulations. Simultaneously, the Department of Justice (the DOJ) is also currently investigating a complaint related to these issues under the Federal False Claims Act. At this stage of the proceedings, the company cannot conclude that the likelihood of an unfavourable outcome is either probable or remote," the filing said.



In an SEC filing, Dr Reddy's said the issue was related to compliance with special packaging of child-resistant blister packs for six products sold by the company in the US

In May 2012, the CPSC had requested Dr Reddy's Laboratories Inc, a wholly-owned subsidiary of the company in the US, to provide certain information with respect to compliance with requirements on special packaging for child-resistant blister packs for six products, as mentioned earlier. The company provided the requisite information.

The CPSC subsequently alleged in a letter dated April 30, 2014 that the company violated the Consumer Product Safety Act and the Poison Prevention Packaging Act (PPPA) and intends to seek civil penalties. Specifically, the CPSC asserted, among other things, that from or about 14 August 2008 through June 1, 2012, the company sold prescription drugs having unit dose packaging that "failed to comply" with the CPSC's special child resistant packaging regulations under the PPPA and failed to issue general certificates of conformance.

Regulatory