

US FDA Refuses to Sweeten Indian Drug Cos' Bitter Pill

Hamburg rejects Ranbaxy plea to allow exports from banned units

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NEW DELHI

The head of the US drug regulatory body has turned down Ranbaxy Laboratories' plea to allow drug-makers to continue exporting from banned manufacturing facilities while they take remedial measures to rectify the issues flagged.

This request was made on Tuesday by Ranbaxy Managing Director Arun Sawhney at a closed-door meeting of CEOs of leading Indian pharmaceutical companies with US Food and Drug Administration (US FDA) Commissioner Margaret Hamburg, who is currently visiting India.

According to two persons present at the meeting, Sawhney told Hamburg that the company was in 'anguish' because of successive actions of the US regulator. He asked her to consider framing a policy which would allow drugmakers to continue doing business in the US so that they could generate money for expensive remedial measures.

In her polite but detailed response, Hamburg said US FDA cannot change the laid-down rules to make such concessions and while companies were engaged in talks for one-off lapses, persistent mistakes were taken very seriously.

FDA Upping Vigilance in India ►► 20

No Relief in Sight

RANBAXY SOUGHT RELIEF FROM FDA

Company wanted to be allowed to export while it took corrective steps

Beleaguered drugmaker said corrective steps were expensive

Allowing it to continue exports would help it finance remedial measures



Regulatory