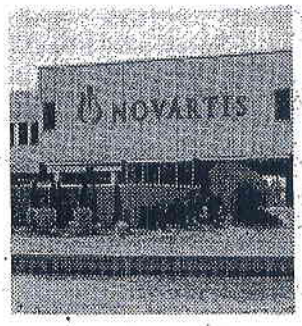
PRESS INFORMATION BUREAU
पत्र सूचना कार्यालय
GOVERNMENT OF INDIA
भारत सरकार

Asian Age, Delhi
Thursday 29th October 2015, Page: 15
Width: 4.56 cms, Height: 20.35 cms, a4, Ref: pmin.2015-10-29.35.159



FDA WARNS NOVARTIS ON 2 INDIA UNITS

New Delhi, Oct. 28: Sandoz, the generic drug arm of Swiss drug major Novartis, has received a warning letter from the US health regulator for violations of current good manufacturing practice (cGMP) norms at its two plants in Western India.

"On October 22, 2015, the US Food and Drug Administration (USFDA) issued a warning letter to our Sandoz Division concerning their Indian sites in Kalwe and Turbhe," Novartis AG said in its quarterly result statement.

Both Turbhe and Kalwe fall in Maharashtra.

The warning letter observations follow USFDA inspection at both sites in August 2014 and are related to deficiencies in current good manufacturing practice for finished pharmaceuticals, it added.

"The warning letter does not contain any new issues versus the 483 observations issued following the inspection in August 2014, which Sandoz has been addressing since then," it said. At Turbhe, Sandoz produces active pharmaceutical ingredients while oral tablets are produced in Kalwe. — *PTI*

Company