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USFDA issues 'import alert' on IPCA Labs

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"We refer to our letter dated July 24, 2014 informing you about the outcome of USFDA inspection at our active pharmaceutical ingredients (APIs) manufacturing facility situated at Ratlam (Madhya Pradesh), during which the company received certain inspection observations in Form FDA 483 from the USFDA, consequent to which the company voluntarily decided to temporarily suspend API shipments from this manufacturing facility for the US markets till this issue is addressed. We now wish to inform you that USFDA has issued an import alert to the said manufacturing facility on January 22, 2015," IPCA noted.

However, the following four API's manufactured at the said manufacturing facility are excluded from the import alert:

1. Hydroxychloroquine Sulfate
2. Propanolol Hydrochloride
3. Trimethoprim
4. Ondansetron

"We are fully committed in resolving this issue at the earliest. We are also committed to our company's philosophy of highest quality in manufacturing, operations, systems, integrity and cGMP culture," it said.