Document-shredding by Indian drug firms raises FDA eyebrows

Ari Altstedter

One Indian pharmaceutical firm’s nighttime document-shredding and potential manufacturing lapses at two others since December are reigniting concerns that, despite recent efforts, the country’s generic-drug industry still has a way to go to gain the trust of US regulators.

US Food and Drug Administration inspectors observed paperwork being shredded at 1 am in the document storage area of a factory owned by Hetero Labs, according to a report on the regulator’s website. Separately, two other drugmakers, including India’s largest, were informed of potential factory violations last month. The news prolongs a four-year wave of unfavourable reports from the FDA for India’s pharmaceutical industry that have crimped revenue in its largest export market. It also comes amid speculation the US may try to reduce its reliance on foreign-made pharmaceuticals after president Donald Trump indicated after being elected a need to ensure drugs sold in the US are made there.