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USV, Canton Labs got warning letters from USFDA in Feb

fe Bureau

Mumbai, March 12: It's not just the big players who are mired in regulatory trouble with the US Food and Drug Administration. In February, two unlisted Indian companies got warning letters from the regulator on issues identified in manufacturing.

Mumbai's USV's Govandi facility was inspected by the USFDA between June 7 and 11, 2013. The warning letter listed issues with laboratory control mechanisms and issues with authorised personnel handling records.

"The lack of reliability and accuracy of data generated by your firm is a serious (manufacturing) deficiency that raises concern for all data generated by your firm," the USFDA said in the letter.

"While we acknowledge the commitment in your response that your staff is being interviewed to determine the extent of the problematic laboratory activities, we remain concerned about the capability and credibility of your quality unit," it added.

USV ranks among the top-20 companies in India, based on AIOCD AWACS data for February 2014. The company, which has four production facilities, said it had sales of ₹17,570 crore in FY14. It manufactures APIs, peptides, biosimilars, injectables, ophthalmics and solid orals.

Separately, the regulator also hauled up Gujarat-based Canton Laboratories citing deficiencies observed in its Vadodara facility. The USFDA raised four issues ranging from issues identified in laboratory testing, inadequate maintenance of data from tests conducted, and cleanliness of equipment.

"Specifically, during three separate walk-throughs of the facility over five days, our inspection found what appeared to be product residue in the (equipment) despite the "clean" label on the equipment. This represents a potential for cross-contamination of the APIs manufactured in this equipment," the US FDA noted in the letter dated February 27.

Regulatory.