

US FDA seals pharma unit of XL Orthomed in India

July 22, 2013 | Regulatory | By BioSpectrum Bureau



Singapore: The US FDA has sealed one of the manufacturing units owned by Indian company, XL Orthomed.

The Sarai Khawaja unit in Faridabad was inspected by the FDA in 2011 along with FDA officials from the Central Drugs Standard Control Organisation (CDSCO).

The regulatory body had then found many 'shortcomings of serious nature' at the plant that manufactures sterile and non-sterile orthopaedic implants. The Haryana State Drugs Controller had directed the firm to overcome the shortcomings, but the firm didn't 'mend its ways'.

An FDA spokesperson said that these come under the definition of 'drug', which was unlicensed. He added that during the raid, the firm was found manufacturing sterile orthopaedic implants without holding a drug manufacturing licence.

The firm had manufactured sterile orthopaedic implants without maintaining the required clean room conditions either, which could be harmful to patients to whom these orthopaedic implants were to be implanted.