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US FDA delegation to visit India in March third week

fe Bureau

New Delhi, March 13: A high-level delegation of the US Food and Drug Administration (USFDA) is set to visit India in the third week of March to discuss the various parameters of the pharmaceutical manufacturing facilities in the country.

The visit is a part of the joint working group between India and the US, that follows the USFDA commissioner Margaret Hamburg's visit a month ago.

"A delegation will meet officials here in the third week of March. They will come to discuss our pharma manufacturing facilities," said commerce and industry minister Anand Sharma. He said Indian drug companies were complying with the WHO GMP and the cooperation between the regulators in the two countries would help the plants to adhere to the standards. The parameters being evaulated relate to process capability, development and manufacturing of manufacturing sites.

The discussion around manufacturing facilities assumes significance as the recent moves by the US FDA for levy of high fees and stringent audit of Indian pharmaceutical facilities is seen as a non-tariff trade barrier move by the US discourage Indian imports. Also, there has been an increase in warning letters to Indian exporters in the recent past and mostly related to data integrity is a cause of concern.

Hamburg had said that many Indian companies that understand GMP have been overshadowed by recent lapses in quality at a handful of pharmaceutical firms. "The problems, encountered by FDA investigators in India, are similar to those seen around the world in manufacturing," she had said.

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