# US FDA to restart onsite checks from next week

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The FDA has developed a rating system to determine when and where domestic inspections can be conducted safely. (Reuters image)

The US Food and Drug Administration (FDA) said that it will resume its onsite inspections of regulated facilities next week after four months of suspended activities because of the coronavirus pandemic.  The FDA had previously announced on March 10 that routine domestic inspections would be put on hold to protect the health of its inspectors. The regulatory body said that it would be running its operations following the guidance issued by the US Centers for Disease Control and Prevention (CDC) and the White House for Opening Up America Again.

“The FDA will resume prioritised domestic manufacturing inspections the week of July 20 after a four-month moratorium on most on-site walkthroughs,’’ FDA commissioner Stephen Hahn

place by state and local governments,'' Hahn said. "In order to move to the next phase, we must see downward trends in new cases of Covid-19 and hospitalisations in a given area."

The FDA has developed a rating system to determine when and where domestic inspections can be conducted safely. The three-part rating system will indicate whether to conduct only mission-critical inspections, conduct all inspections with safeguards to protect staff that have self-identified as being part of a vulnerable population, or resume all normal regulatory activities in a given geographic area.

Incidentally, Indian pharma firms had asked the FDA to consider alternative measures to inspect facilities, arguing that a ban on most inspections hindered their ability to distribute key drugs. Reports say that in mid-April, Indian pharmaceutical firms had requested the FDA to conduct "desk reviews" or virtual facility inspections during the pandemic in order to ensure the continuous supply of much-needed drugs in the US.

"The members of Indian Pharmaceutical Alliance (IPA) had asked for virtual reviews of facilities that are new and are slated to produce a new class of drugs or have completed a corrective action plan following a previous inspection failure,'' a member of IPA said. IPA had also requested the FDA to consider recognising inspections by foreign regulators and temporarily waiving on-site inspections based on past inspection history and the critical nature of products, such as drug shortages or products that do not currently have generic alternatives. However, there is no confirmation from the regulating agency for conducting virtual inspections as on date.