US- FDA (Food and Drug Administration)’s Form 483

Why in news?

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> Issuance of Form 483 observations, warning letters and import alerts from the FDA poses a key risk for Indian pharma companies exporting drugs to US.

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What FDA does?

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- The FDA exercises authority for inspections of facilities in foreign countries which supply pharma products to the US.
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- So, pharma plants in India that export to the US must adhere to the **cGMP (current good manufacturing practices)** as per FDA guidelines.
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- FDA officials often visit the facilities to check compliance with the rules.
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- FDA issues Form 483 at the completion of inspection.
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What is Form 483?

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- If FDA finds deviations from cGMP, it is mentioned in the Form 483.
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- The form specifies areas in which the facility fell short of regulatory expectations.
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- It is then presented and discussed with the management of the company.
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- Along with the Form 483, the FDA also issues **an Establishment Inspection Report (EIR)** which specifies whether action is required to be taken.

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What will happen then?

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- The FDA calls for a response to the Form 483 observations within 15 working days.
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- Though a written response is not mandatory, it is preferred so that a warning letter can be avoided.
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- The company has to respond to the observations in detail with reasons for the shortcomings and corrective action plans.
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- If the management does not convincingly address the Form 483 observations within the specified time period, the FDA issues a warning letter.
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- Sometimes, if the observations are of a severe nature, the FDA may issue a warning letter even without issuing Form 483.
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- Unsatisfactory response to the warning letter could lead to further action including import alert for products or the facility, withholding of product approval, and suspension or cancellation of manufacturing license.
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Why is it important?

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- The USA is the major market for several Indian pharma companies.
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- Indian companies have become dominant players in the US generic drugs space.
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- But over the past few years, there has been an increase in the issue of Form 483s which further led to warning letters.
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- Over the past four years, **India received the highest number of warning letters** issued to a single country.
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- Also, the number of warning letters received by Indian companies has

increased over these years.
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- The timeline for problem redressal and re-inspections have also lengthened.
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- If the regulatory crackdown continues, it could put a question mark on the growth story of many such companies.
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- Quick, satisfactory redressal of Form 483 observations is therefore important to stop further escalations to warning letters and more.
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Why should we care?

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- If we have invested in pharma stocks, it makes sense to keep a close watch on FDA inspections and outcomes.
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- Many pharma stocks have been negatively impacted in the recent past due to adverse Form 483 observations and their escalations into warning letters and import alerts.
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- On the other hand, getting FDA clearances after re-inspection of facilities have seen pharma stocks rally sharply.
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Source: Business Line

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