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

## Why in news?

\n\n

> 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.

\n\n

## What FDA does?

\n\n

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

\n\n

## What is Form 483?

\n\n

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

\n

\n\n

## What will happen then?

\n\n

\n
- The FDA calls for a response to the Form 483 observations within 15 working days.
\n
- Though a written response is not mandatory, it is preferred so that a warning letter can be avoided.
\n
- The company has to respond to the observations in detail with reasons for the shortcomings and corrective action plans.
\n
- If the management does not convincingly address the Form 483 observations within the specified time period, the FDA issues a warning letter.
\n
- Sometimes, if the observations are of a severe nature, the FDA may issue a warning letter even without issuing Form 483.
\n
- 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.
\n

\n\n

## Why is it important?

\n\n

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

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

\n\n

## Why should we care?

\n\n

\n
- If we have invested in pharma stocks, it makes sense to keep a close watch on FDA inspections and outcomes.
\n
- 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.
\n
- On the other hand, getting FDA clearances after re-inspection of facilities have seen pharma stocks rally sharply.
\n

\n\n

\n\n

**Source: Business Line**

\n

