



Review Article

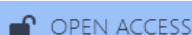
Impact of USFDA 483s on Warning Letters

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ABSTRACT

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Objectives: This review looks at how United State Food and Drug Administration (USFDA) Form 483 observations are linked to warning letters, especially for Indian pharmaceutical companies. **Methodology:** The study focuses on drug manufacturers and uses data from inspections and warning letters between January 2023 and November 2024. It also compares some older data from 2018 to 2020 to see changes over time. The researcher studied several sources, including regulatory guidelines like USFDA, World Health Organization (WHO), and European Union good manufacturing practices (EU GMP), to understand current good manufacturing practices (cGMP) and why companies fail to meet them. **Results:** The findings show that if company gets a Form 483 during an inspection, there is a more than 50% chance it may get warning letter later, especially if the company has failed to reply properly. Over the past two years, 20 Indian companies obtained letters. Out of these, 10 already had 483 observations earlier, while others failed their first inspection due to serious good manufacturing practices (GMP) problems. The review concludes that many warning letters happen because of poor GMP compliance and weak follow-up after past inspections. Future research can help companies avoid such issues by improving quality systems. This can lead to better product safety and help companies save time and money.

Keywords: cGMP, Data Integrity, Form 483, No Action Indicated (NAI), Official Action Indicated (OAI), USFDA, Voluntary Action Indicated (VAI), Warning Letter.

INTRODUCTION

The Food and Drugs Administration (FDA) is responsible for ensuring that pharmaceutical, medical device, and food products meet the highest standards of safety, effectiveness, and conformity with regulatory requirements (DeBell & Chesney, 1982; Doherty, 1980). A critical tool used by the USFDA during inspections is FDA Form 483, which is issued when inspectors identify conditions or practices that may violate federal regulations, particularly those associated with Current Good Manufacturing Practices (cGMP) (FDA Form 483 FAQ, n.d.; USFDA 21 CFR Part 211, n.d.). The Form 483 serves as an official record of these inspectional observations and highlights areas where companies may be out of compliance (Kiernan, 1988; Pazhayatil et al., 2019).

While receiving a Form 483 does not constitute an enforcement action, it indicates that the FDA has identified issues that require correction and may lead to regulatory consequences if not adequately addressed (Winchell, 2011; Patel, 2012). These observations may span several operational domains, including manufacturing processes, quality control, documentation systems, personnel training, and environmental controls (Ananth et al., 2018; Saini et al., 2022).

USFDA 483 Observation Classifications

The USFDA 483 findings are grouped into three main categories (Figure 1a) based on how serious the findings are and what action the FDA recommends (FDA Form 483 FAQ, n.d.).

Official Action Indicated (OAI)

This classification means that the FDA found serious regulatory issues site inspection, and further actions are expected. These actions could include a Warning Letter, product recalls, or even shutting down the facility (Church & Mahoney, 2009; Kiernan, 1988). OAI classifications are usually given when the FDA believes there is a significant risk regarding product quality or patient safety that requires immediate attention (Pazhayatil et al., 2019).

No Action Indicated (NAI)

The NAI classification means that the issues observed in the course of the inspection were not serious enough to require further regulatory steps from the FDA. It indicates that there were no major risks to product safety, and the problems can usually be fixed internally without the need for the agency to take additional steps. However, companies are still expected to correct any issues raised during the inspection (DeBell & Chesney, 1982; Doherty, 1980).

Voluntary Action Indicated (VAI)

The VAI classification means that the FDA found some issues throughout the inspection but believes the company can fix them on its own without needing official action. The company is anticipated to take corrective steps and usually needs to submit a response explaining how they will correct the issues (Winchell, 2011; Patel, 2012).

The classification of USFDA 483 observations plays a crucial role in determining the level of regulatory scrutiny a company will face. Warning Letter or additional enforcement actions are often issued based on the classification of observations. If the observations are not resolved in a timely and effective manner, it can result in serious impact on the company, such as delays in product approval, market withdrawal, or reputational damage (Ananth et al., 2018; Saini et al., 2022).

Figure 1b shows the flow of USFDA inspection (USFDA Inspection Classification Database, n.d.).



Figure 1a:
USFDA 483 Observation Category.

Figure 1b:
Flow of USFDA Inspection.

Regulatory Guidelines

21 Code of Federal Regulation (CFR) Part 211: Current Good Manufacturing Practice for Finished Pharmaceuticals, 21 CFR Part 210 cGMP in Manufacturing, Processing, Packing, or Holding of Drugs (USFDA, 2023).

Various regulatory frameworks and guidelines govern data integrity in the pharmaceutical industry like WHO Technical Report Series 1033 - Annex 4: WHO Guideline on data integrity in 2021 (WHO, 2021), US FDA has established guidelines such as 21 CFR Part 11, which addresses electronic records and electronic signatures and also in Part 211 (211.68, 211.100 and 211.160, 211.180, 211.188, 211.194, and 212.60(g)) which include the requirement for data integrity (USFDA, 2023). This regulation outlines requirements for ensuring the accuracy, authenticity, and security of electronic data (USFDA, 2023).

Pharmaceutical Inspection Co-operation Scheme (PIC/S GUIDANCE) on good practices for data management and integrity in regulated GMP/Good Documentation Practice (GDP), environments in July 2021 (PIC/S, 2021), European Commissions (EC) EudraLex Volume 4 has set requirement for documentation (European Commission, 2022).

METHODOLOGY

The researcher has reviewed a range of articles, USFDA Form 483 observations, and letters sent to pharmaceutical companies over the past two years (2023 and 2024) (USFDA, 2024, Form 483 Database; USFDA, 2024, Warning Letters Database). In addition, regulatory guidelines for cGMP compliance, such as those from WHO TRS, USFDA, and EU GMP, were examined (WHO, 2021, TRS 1033; USFDA, 2022, 21 CFR Parts 210–211; European Commission, 2020,

EudraLex Volume 4). The researcher also explored proposed research-related websites to gather additional information and deepen their understanding of the subject matter, as well as to gain insight into the perspectives of other researchers. This study evaluates cGMP violations based on the US FDA Form 483 observations for the years 2024 and 2023 (USFDA, 2024, Form 483 Database), along with warning letters issued to Indian pharmaceutical companies from January 2023 to November 2024 (USFDA, 2024, Warning Letters Database). Data from the years 2018 to 2020 are included solely for comparative purposes (see Table 1) (USFDA, 2020, Form 483 Database). The analysis focuses on reviewing findings recorded in the 483 forms and warning letters within the pharmaceutical (only drug manufacturer) industry. Other sectors, such as medical devices and food, received warning letters; those are excluded from this study (refer to Figure 2) (USFDA, 2024, Warning Letters Database).

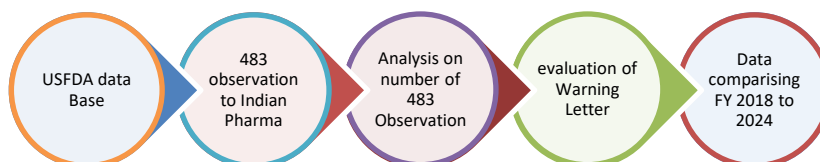


Figure 2: Methodology

Table 1: Number of 483 Form & Warning Letter

| Year | 483 Form | Warning Letter | % of warning letter against 483 Observation |
|------|----------|----------------|---|
| 2024 | 147 | 8 | 5.44 |
| 2023 | 150 | 12 | 8.00 |
| 2020 | 134 | 14 | 10.45 |
| 2019 | 227 | 25 | 11.01 |
| 2018 | 198 | 9 | 4.55 |

Table 1 shows the number of companies having USFDA observation in form 483 & warning letters from the year 2018 to 2024 in India (USFDA, 2018 - 2024, Form 483 & Warning Letters Database). And Figure 3 shows Graphical presentation for 483 Form & warning letter FY 2018–2024.

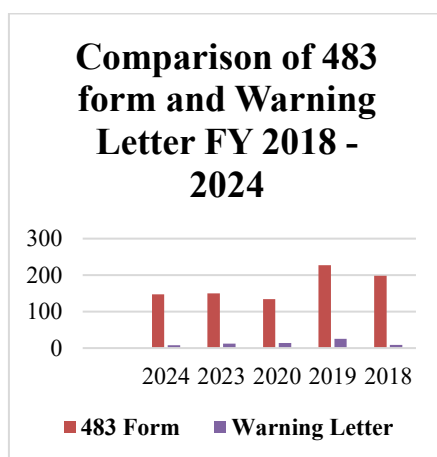


Figure 3: Graphical presentation for 483 Form & warning letter FY 2018 – 2024.

2021 and 2022 were covid pandemic situation, and hence audit was not conducted; however, some companies had warning letters which are not listed in the above-said table (USFDA, 2022, Warning Letters Database). Below Table No. 2 shows company name were received 483 observations and warning letters.

Table 2: List of Companies received Warning letter and 483 Form.

| Warning Letter Issue Date | Company Name | 483 Form Received | |
|---------------------------|----------------------------------|-------------------|----|
| | | Yes | No |
| 03/28/2024 | Kilitch Healthcare India Limited | Yes | |
| 07/17/2024 | Velocity Pharma LLC | | No |
| 07/25/2023 | Baxter Healthcare Corporation | | No |
| 04/08/2024 | Natco Pharma Limited | Yes | |

| | | | |
|------------|--|-----|----|
| 07/20/2023 | Medgel Private Limited | Yes | |
| 11/06/2024 | Unexo Lifesciences, Private Limited | | No |
| 02/01/2024 | Madhu Instruments Private Limited | Yes | |
| 11/17/2023 | Cipla Limited | Yes | |
| 04/10/2023 | Champaklal Maganlal Homeo Pharmacy Private Limited | | No |
| 08/03/2023 | Suhan Aerosol | | No |
| 08/03/2023 | Orchid Lifesciences | | No |
| 12/15/2023 | Patcos Cosmetics Pvt. Ltd. | | No |
| 07/28/2023 | Intas Pharmaceuticals Limited | Yes | |
| 03/27/2024 | Vintage Chemical Inc. | | No |
| 06/05/2023 | Centaur Pharmaceuticals Private Ltd. | Yes | |
| 07/25/2023 | Centaur Pharmaceuticals Private Ltd. | Yes | |
| 04/20/2023 | Accra-Pac, Inc. dba Voyant Beauty | | No |
| 05/11/2023 | Remedy Repack, Inc. | | No |
| 08/15/2024 | Eugia Pharma Specialities Limited | Yes | |
| 10/16/2023 | Sun Pharmaceutical Industries Ltd. | Yes | |
| 06/11/2024 | ARG Laboratories, Inc. | | No |

Ethical Consideration

This review relies solely on information already available in the public regulatory domain and does not include any form of human or animal involvement. Since no experimental work or personal data collection was carried out, formal ethical clearance was not required for this study.

RESULTS

The review of Tables 1, 2, and 3 indicates that companies receiving USFDA Form 483 observations during inspections face a greater than 50% likelihood of subsequently receiving a warning letter, depending on the adequacy of their compliance response. As shown in Figure 4, the proportion of Official Action Indicated (OAI) outcomes over the past five years remains significant, with nearly 10% of cases falling under OAI, suggesting the presence of major or critical deficiencies requiring corrective measures.

TABLE 3: CATEGORIZATION OF 483 OBSERVATIONS FOR 2024-2018 YEAR.

| Year | 483 Form | | | | No. of Drug Companies who received Warning Letter | General % of Warning Letter against OAI Observation | % of OAI against Total number of Observation |
|------|----------|-----|-----|--------------------------------|---|---|--|
| | OAI | VAI | NAI | Total Number of Drug Companies | | | |
| 2024 | 15 | 89 | 43 | 147 | 8 | 53.33 | 10.20 |
| 2023 | 19 | 86 | 45 | 150 | 12 | 63.16 | 12.67 |
| 2020 | 13 | 82 | 39 | 134 | 14 | 107.69 | 9.70 |
| 2019 | 30 | 121 | 76 | 227 | 25 | 83.33 | 13.22 |
| 2018 | 18 | 108 | 72 | 198 | 9 | 50 | 9.09 |

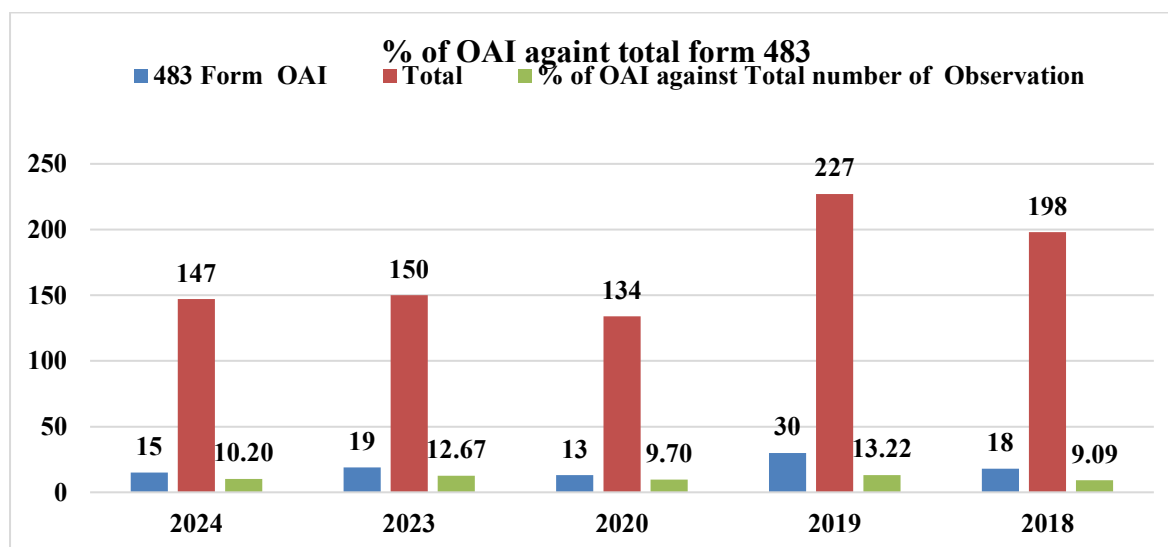


Figure 4: % of OAI presentation FY 2018 – 2024.

In 2023–2024, a total of 20 pharmaceutical firms received warning letters. Among these, 10 companies had already been issued Form 483 observations in earlier inspections, while others received warning letters during their initial inspection due to serious GMP violations and quality-related risks.

DISCUSSION

The observed pattern demonstrates a strong relationship between Form 483 observations and subsequent enforcement actions. Companies with unresolved, repeated, or poorly addressed deficiencies are more likely to receive warning letters. The recurrence of OAI outcomes signals gaps in quality systems, documentation practices, and adherence to cGMP requirements. Moreover, several firms receiving warning letters during their first USFDA inspection highlight the persistence of systemic compliance weaknesses across parts of the pharmaceutical sector. These findings reinforce the need for proactive quality oversight, robust internal audits, and timely corrective and preventive actions.

CONCLUSION

Overall, the analysis suggests that most warning letters issued during the review period stemmed from **GMP non-compliance and insufficient responses** to earlier inspection findings. Continued research on the root causes of Form 483 observations and warning letters will support companies in strengthening their quality systems, preventing recurring deficiencies, and enhancing regulatory readiness. Such improvements will not only help reduce compliance risks but also contribute to better product quality and long-term economic advantages for the industry.

SUMMARY

The analysis shows that pharmaceutical companies receiving Form 483 observations have a strong chance of later receiving USFDA warning letters, especially when earlier deficiencies were not addressed effectively. A review of recent inspection data reveals a consistent number of OAI outcomes, indicating recurring major compliance gaps. In 2023–2024, half of the companies that received warning letters had previously been issued Form 483 observations, while others failed their first inspection due to significant GMP violations. Overall, the findings highlight that many enforcement actions result from weak GMP adherence and inadequate corrective responses. Strengthening quality systems and improving follow-up practices can help companies avoid repeated observations, reduce regulatory risk, and enhance product quality and operational efficiency.

ABBREVIATIONS

CGMP: Current Good Manufacturing Practices; **CFR:** Code Of Federal Regulations; **EC:** European Commission; **EU GMP:** European Union Good Manufacturing Practices; **FDA:** Food And Drug Administration; **FY:** Financial Year; **GDP:** Good Documentation Practice; **GMP:** Good Manufacturing Practices; **NAI:** No Action Indicated; **OAI:** Official Action Indicated; **PIC/S:** Pharmaceutical Inspection Co-Operation Scheme; **USFDA:** United State Food And Drug Administration; **VAI:** Voluntary Action Indicated; **WHO TRS:** World Health Organization Technical Report Series

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Conflict Of Interest: The authors report that they hold no financial or personal interests that could influence this research.

Financial Support and Sponsorship: The authors confirm that the research received no external financial assistance.

Consent For Publication: All ethical considerations were duly addressed by the author and co-author. Since the study relied solely on open-access information from the USFDA database, no individual consent was required.

Availability Of Data and Materials: All data relevant to this study are included in the manuscript. Additional underlying datasets are available from the author upon justified request.

Author Contributions: The development of this review article was achieved through the committed efforts of the author and co-authors in collecting the data and performing its analysis and interpretation.

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