Recall Enterprise System (RES) Data Quality Improvements to Address Opioid Epidemic

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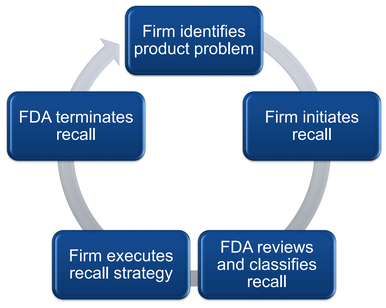
Abstract

Drug Recalls are typically voluntary actions taken by firms to remove or correct products that are in violation of the Food, Drug, and Cosmetic Act to protect the public health. Recalls associated with opioid products are of particular interest. Opioid addiction and abuse have created an immense public health crisis, and the death toll is staggering. The FDA evaluates recall information provided by firms including the identified *Responsible Firm,* the firm where the adulteration or misbranding associated with the occurred.

Figure 1. Human Drug Product Recall Lifecycle



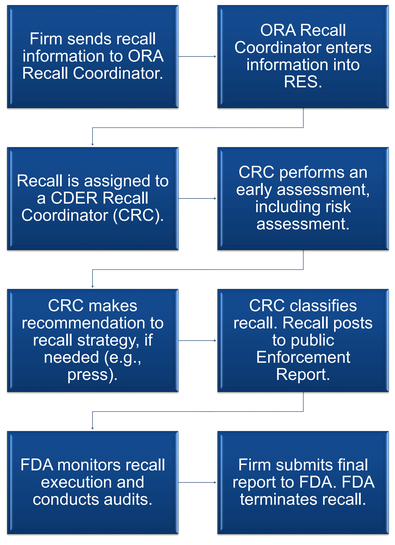
The Center for Drug Evaluation and Research (CDER) has examined hundreds of drug recalls in the FDA's Recalls Enterprise System (RES) and identified missing or inconsistent *Responsible Firm* data. Missing or inconsistent information can lead to delays and errors in the identification of firms that are responsible for problematic drug products, including opioid products, as well as inaccurate scoring (i.e., prioritization) for routine surveillance of these sites. Targeting firms that are responsible for manufacturing or distributing unsafe and ineffective opioid products is critical to FDA's mission and efforts to address the opioid epidemic.

Introduction

CDER's Office of Compliance, in collaboration with CDER's Office of Pharmaceutical Quality (OPQ) and the Office of Regulatory Affairs (ORA), has evaluated the accuracy of the *Responsible Firm* information generally provided when a recall is initiated. It was observed that the Firm Establishment Identifier (FEI) number for these firms was either inaccurate or missing in a substantial number of recalls.

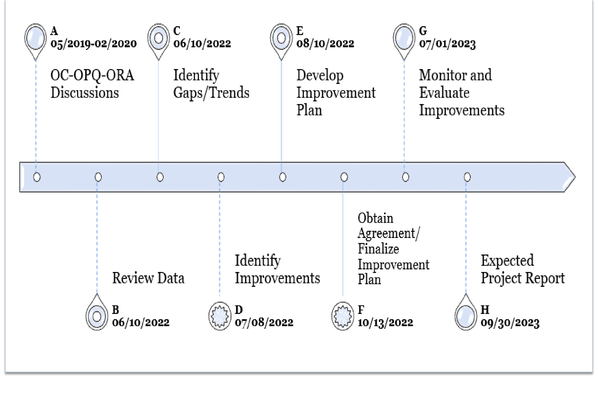
CDER uses accurate FEI data to ensure sites associated with recall events are properly monitored. Identifying these firms facilitates the FDA's response to product quality issues and allows accurate site selection model scoring for surveillance inspections.

Figure 2. Review and Classification Review Process



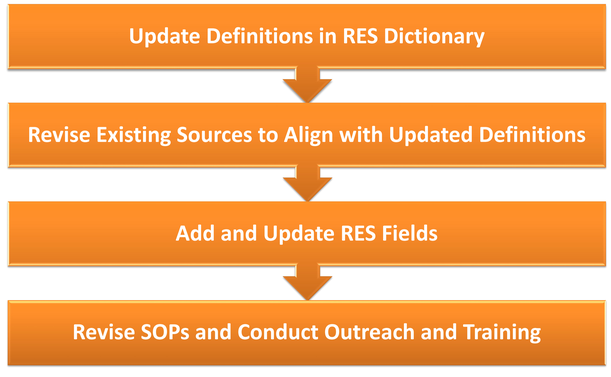
Materials and Methods

Figure 3. RES Project Improvement Timeline



A multi-disciplinary group of experts retrieved and evaluated all recall data from RES over the past four fiscal years (FY2020-2023) to identify the number of recalls that had inaccurate or missing *Responsible Firm* information. The group conducted a cross-reference evaluation using various internal FDA data sources against recall information provided by firms. After data review, the group evaluated current processes to identify potential improvements. The group's proposed recommendations included making the *Responsible Firm* field in RES mandatory, updating RES field definitions, revising data entry procedures, and training. The group also considered including opioid-specific fields in RES to better track data for these critical products.

Figure 4. Process Improvements Initiated in FY2023



Results and Discussion

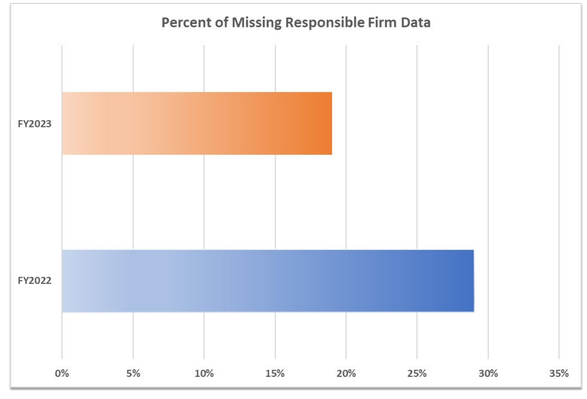
Figure 5. Number of Human Drug Product Recalls with Missing Responsible Firm Information (FY2020-FY2023*)

Fiscal Year	Total Events	Total Events w/Missing Responsible Firm	Percent of Events w/Missing Responsible Firm
FY2020	367	73	20%
FY2021	317	63	20%
FY2022	344	100	29%
FY2023**	129	24	19%

* Improvements initiated at end of FY2022. ** FY2023 data to date.

Data for missing *Responsible Firm* information at time of recall classification are presented and stratified by fiscal year as cumulative numbers and percentages. An increase in the percentage of missing *Responsible Firm* data was observed from 20% in FY2020 to 29% in FY2022. Since the process improvements were initiated at the end of FY2022, there has been a noticeable reduction in the percent of missing information from 29% for FY2022 compared to 19% for FY2023 data to date.

Figure 6. Improvement in Identification of Responsible Firm FY2022-FY2023



Full implementation of all improvement recommendations and review of *Responsible Firm* data entry will continue for the remainder of FY2023 to monitor process improvements.

Conclusion

The RES process improvements associated with these efforts were initiated to enable the FDA to achieve higher levels of accuracy, completeness, and consistency in the identification of *Responsible Firms* information, site scoring, and overall recall data. The enhancements will allow the FDA to have a more effective oversight of the drug industry and focus efforts on firms found to be responsible for the reason for recalls. Further, by achieving the desired outcome, CDER will be able to better conduct swift and effective recall-specific actions to help ensure that consumers are not falling prey to violative opioid products.