

Postmarketing Adverse Event Reporting Compliance Program

Postmarketing safety data collection and adverse event reporting are critical elements of FDA's oversight of drugs and therapeutic biologics available to the American public. The testing that helps to establish the safety of products, such as drugs and therapeutic biologics, is typically conducted on small groups before FDA approves the products for sale. Some problems can remain unknown, only to be discovered when a product is used by a large number of people.

FDA [reviews postmarketing safety information \(/drugs/surveillance/postmarketing-surveillance-programs\)](#) and [conducts postmarketing adverse event reporting inspections \(/media/84969/download\)](#) of companies to evaluate compliance with laws and regulations, assess the risks to patients, and determine appropriate actions based on findings during inspections. See [Bioresearch Monitoring Program \(/inspections-compliance-enforcement-and-criminal-investigations/fda-bioresearch-monitoring-information/bioresearch-monitoring-program-information\)](#) for more information.

Companies with approved applications for drugs and therapeutic biologics as well as manufacturers, packers and distributors listed on product labels must submit postmarketing safety information to FDA. These requirements also apply to companies marketing unapproved prescription drugs or over-the-counter drugs as well as retailers whose name appears on the product label as a distributor.

FDA relies on complete, accurate and timely safety information to evaluate a product's safety profile and uphold its mission to protect and promote public health.

Failure to comply with postmarketing adverse event reporting regulations may result in compliance actions. The agency may take enforcement action if issues found during inspections are not promptly and adequately corrected.

What is an adverse event?

An adverse event is any unanticipated experience or side effect associated with the use of a drug or therapeutic biologic in humans, whether or not it is considered related to the product. An adverse event could occur:

- with use in professional practice

Feedback

- from overdose whether accidental or intentional
- from abuse
- from withdrawal
- due to lack of expected effectiveness

During inspections, FDA investigators will review a company's postmarketing adverse event information to ensure compliance with federal laws and regulations.

Elements for reporting postmarketing adverse events

These data elements are required for valid adverse event submissions and are evaluated during inspections:

- Identifiable patient
- Suspect drug or biological product
- Adverse event or report of death
- Identifiable reporter

Postmarketing adverse event reporting compliance inspections

FDA may inspect:

- Companies with an approved product application (NDA, ANDA and BLA) regardless of whether the product is marketed
- Other stakeholders (e.g., manufacturers, packers, distributors, and retailers named on the product label)
- Entities contracted to process adverse event information on behalf of companies or other supply chain stakeholders

How to report an adverse event

Consumers, caregivers and health care professionals: Submit electronically using MedWatch (<https://www.accessdata.fda.gov/scripts/medwatch/>). See How Consumers Can Report an Adverse Event or Serious Problem to FDA ([/safety/reporting-serious-problems-fda/how-consumers-can-report-adverse-event-or-serious-problem-fda](https://www.fda.gov/safety/reporting-serious-problems-fda/how-consumers-can-report-adverse-event-or-serious-problem-fda)) for more information.

Companies with approved applications or companies named on the product label: Submit adverse events electronically to FDA using electronic submissions gateway (ESG) or safety reporting portal (SRP). See FDA Adverse Event Reporting System (FAERS) Electronic Submissions ([/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-](https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-)

[adverse-event-reporting-system-faers-electronic-submissions](#)) and [Questions and Answers on FDA's Adverse Event Reporting System \(FAERS\)](#) ([/drugs/surveillance/questions-and-answers-fdas-adverse-event-reporting-system-faers](#)) for more information.

First time users may [create an ESG account](#) ([/industry/electronic-submissions-gateway/create-esg-account](#)) or request a [SRP account](#) ([/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-electronic-submissions](#)) to submit an electronic report.

See [Postmarketing Adverse Event Reporting – Required Information](#) ([/drugs/surveillance-post-drug-approval-activities/postmarketing-adverse-event-reporting-required-information](#)) for specific requirements with adverse drug event reports.

Additional resources

- [Postmarketing Safety Reporting for Combination Products Guidance for Industry and FDA Staff](#) ([/media/111788/download](#))
- [Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications](#) ([/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications](#))
- [Providing Postmarket Periodic Safety Reports in the ICH E2C\(R2\) Format \(Periodic Benefit-Risk Evaluation Report\)](#) ([/regulatory-information/search-fda-guidance-documents/providing-postmarket-periodic-safety-reports-ich-e2cr2-format-periodic-benefit-risk-evaluation](#))
- [Providing Submissions in Electronic Format — Postmarketing Safety Reports](#) ([/regulatory-information/search-fda-guidance-documents/providing-submissions-electronic-format-postmarketing-safety-reports](#))
- [Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic](#) ([/regulatory-information/search-fda-guidance-documents/postmarketing-adverse-event-reporting-medical-products-and-dietary-supplements-during-pandemic](#))
- [Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application](#) ([/regulatory-information/search-fda-guidance-documents/postmarketing-adverse-event-reporting-nonprescription-human-drug-products-marketed-without-approved](#))

- [Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines \(/regulatory-information/search-fda-guidance-documents/postmarketing-safety-reporting-human-drug-and-biological-products-including-vaccines\)](#)
- [Processes and Practices Applicable to Bioresearch Monitoring Inspections \(/regulatory-information/search-fda-guidance-documents/processes-and-practices-applicable-bioresearch-monitoring-inspections\)](#) (December 2025)

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