Drug/Biologic/Human Cell, Tissues and Cellular and Tissue-Based Product Manufacturers, Distributors, and Packers

Information on mandatory reporting:

Applicable Regulations
You can search the FDA’s CFR Title 21 Database for the latest regulations. The links below will take you directly to the relevant section.

- **Drugs**
  - 21 CFR 310.305 -- Records and reports concerning adverse drug experiences on marketed prescription drugs for human use without approved new drug applications.
  - 21 CFR 312.32 -- IND Safety Reports.
  - 21 CFR 314.80 -- Postmarketing reporting of adverse drug experiences.

- **Biologics**
  - 21 CFR 312.32 -- IND Safety Reports.
  - 21 CFR 600.80 -- Postmarketing reporting of adverse experiences.
  - 21 CFR 1271.350 -- Human Cells, Tissues, and Cellular and Tissue-Based Product Reporting

Guidance for Industry
- [Guidances on Electronic Submissions](#)
- Postmarketing Reporting of Adverse Experiences
  - [Regulations and Policies and Procedures for Postmarketing Surveillance Programs](#)
  - [Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines](#)
  - MedWatch Form FDA 3500A: Mandatory Reporting of Adverse Reactions Related to Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)
Referencing FDA’s MedWatch Program

Contact information for questions about mandatory reporting

Where to send mandatory reporting forms

MedWatch to Manufacturer Program

Adverse Events Reporting System (AERS) Electronic Submissions

- Postmarketing expedited and periodic individual case safety reports with and without attachments acceptable in electronic format without paper records (effective November 29, 2001)

International Conference on Harmonization (ICH)

- Efficacy
- Joint Safety/Efficacy (Multidisciplinary)
- Quality
- Safety

Federal Register Publications Related to Postmarketing Reporting

[External link to the Federal Register Search]

- 5/04/2001: Providing Regulatory Submissions in Electronic Format - Postmarketing Expedited Safety Reports; Availability - NOTICE
- 3/12/2001: Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines; Availability - NOTICE
  [Docket No. 98N-0750] Vol. 63, No. 214, pg. 59746 - 59750
- 10/07/1997: Expedited Safety Reporting Requirements for Human Drug and Biological Products - Final Rule (21 CFR Parts 20, 310, 312, 314, and 600)
06/25/1997: **Postmarketing Expedited Adverse Experience Reporting for Human Drug and Licensed Biological Products; Increased Frequency Reports - FINAL RULE (21 CFR Parts 310, 314, and 600)**
[Docket No. 96N-0108] Vol. 62, No. 122, pg. 34166 - 34168

05/19/1997: **International Conference on Harmonisation; Guideline on Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs; Availability - NOTICE**
[Docket No. 96D-0041] Vol. 62, No. 96, pg. 27470 - 27476

10/1/1996: **International Conference on Harmonisation; Draft Guideline on Data Elements for Transmission of Individual Case Safety Reports; Availability - NOTICE**
[Docket No. 96D-0236] Vol. 61, No.191, pg. 51287 - 51294

04/03/1995: **Protecting the Identities of Reporters of Adverse Events and Patients; Preemption of Disclosure Rules - FINAL RULE (21 CFR Part 20)**
[Docket No. 93N-0334] Vol. 60, No. 63, pg. 16962 - 16968

03/01/1995: **International Conference on Harmonisation; Guideline on Clinical Safety Data Management; Definitions and Standards for Expedited Reporting; Availability - NOTICE**
[Docket No. 93D-0203] Vol. 60, No. 40, pg. 11284 - 11287

[Docket No. 93N-0072] Vol. 59, No. 207, pg. 54034 - 54044

[Docket No. 93N-0181] Vol. 59, No. 207, pg. 54046 - 54064

06/03/1993: **Form for Reporting Serious Adverse Events and Product Problems with Human Drug and Biological Products and Devices; Availability - NOTICE**
[Docket No. 93N-0072] Vol. 58, No. 105, pg. 31596 - 31614