

II.A.2. Postmarketing Safety Reporting Regulations

Sections 310.305, 314.80, 314.98, and 600.80 (21 CFR 310.305, 314.80, 314.98, and 600.80) require expedited reports of postmarketing adverse drug experiences (see table 2). The following persons are subject to these postmarketing expedited safety reporting regulations:

- Applicants with approved NDAs (§ 314.80) and abbreviated new drug applications (ANDAs) (§ 314.98);
- Licensed manufacturers with approved BLAs (§ 600.80);
- Manufacturers, packers, and distributors (also shared manufacturers, joint manufacturers, or any other participant involved in divided manufacturing for § 600.80) whose name appears on the label of a product with

an approved NDA, ANDA, or BLA (§§ 314.80, 314.98 and 600.80); and

- Manufacturers, packers, and distributors whose name appears on the label of a prescription drug product marketed without an approved NDA or ANDA (§ 310.305). In this document, the term “applicant” will be used instead of the term “licensed manufacturer” for persons with approved BLAs.

TABLE 2.—CURRENTLY REQUIRED POSTMARKETING SAFETY REPORTS

Type of report	Safety report	Type of information	21 CFR section	Submission timeframe	Persons with reporting responsibility
Expedited report.	15-day Alert report ..	Serious and unexpected adverse drug experience ¹ .	310.305, 314.80, 314.98, 600.80.	15 calendar days ...	Manufacturers ² and applicants ³ .
	15-day Alert report-followup.	New information for 15-day Alert report.	310.305, 314.80, 314.98, 600.80.	15 calendar days ...	Manufacturers ² and applicants ³ .
	Reports to manufacturer instead of FDA.	Serious adverse drug experiences ¹ .	310.305	5 calendar days	Packers and distributors.
	Reports to applicant instead of FDA.	Serious adverse experiences ¹ .	314.80, 314.98, 600.80.	5 calendar days	Manufacturers, packers, and distributors (§§ 314.80, 314.98, and 600.80) and joint manufacturers, shared manufacturers, or any participant involved in divided manufacturing (§ 600.80).
Expedited report.	Blood safety report ..	Fatalities	606.170	As soon as possible (oral or written) and 7 days (written).	Blood establishments.
Periodic report.	Periodic adverse drug experience report.	<ul style="list-style-type: none"> • Narrative summary and analysis of adverse drug experiences that occurred during the reporting interval including 15-day Alert reports previously submitted to FDA ¹. • Individual case safety report for each adverse drug experience not submitted to FDA as a 15-day Alert report, excluding reports from postmarketing studies, reports in the scientific literature, and foreign marketing experience ¹. • History of actions taken.. 	314.80, 314.98, 600.80.	Quarterly for 3 years from the date of U.S. approval of the application and then annually thereafter.	Applicants.

¹ For spontaneous reports, adverse drug experiences are submitted whether or not they are considered drug related; for study reports, adverse drug experiences are submitted if there is a reasonable possibility that the drug caused the adverse drug experience.

² Section 310.305 also includes packers and distributors.

³ Sections 314.80 and 314.98 also include manufacturers, packers and distributors. Section 600.80 also includes manufacturers, packers, distributors, joint manufacturers, shared manufacturers, or any participant involved in divided manufacturing.

Applicants with approved NDAs, ANDAs, and BLAs must also submit periodic reports of postmarketing adverse drug experiences under §§ 314.80, 314.98 and 600.80 (see table

2). Manufacturers of prescription drug products marketed without an approved NDA or ANDA are not required to submit periodic reports of

postmarketing adverse drug experiences (§ 310.305).

Existing regulations, under § 606.170 (21 CFR 606.170), require expedited reports of fatalities associated with