

Purpose	21 CFR Paragraph and Title
How do the requirements under § 514.80 relate to current good manufacturing practices?	514.80(a)(5).
	514.80(b) Reporting requirements.
What are the requirements for reporting product/manufacturing defects?	514.80(b)(1) Three-day NADA/ANADA field alert report.
	514.80(b)(2) Fifteen-day NADA/ANADA alert report.
What are the requirements for reporting serious and unexpected adverse drug experiences?	514.80(b)(2)(i) Initial report.
What are the requirements for followup reporting of serious and unexpected adverse drug experiences?	514.80(b)(2)(ii) Followup report.
What are the requirements for nonapplicants for reporting adverse drug experiences?	514.80(b)(3) Nonapplicant report.
What are the general requirements for submission of periodic drug experience reports, e.g., forms to be submitted, submission date and frequency, when is it to be submitted, how many copies? How do I petition to change the date of submission or frequency of submissions?	514.80(b)(4) Periodic drug experience report.
What must be submitted in the periodic drug experience reports?	514.80(b)(4)(i) through (b)(4)(iv).
What distribution data must be submitted? How should the distribution data be submitted?	514.80(b)(4)(i) Distribution data.
What labeling materials should be submitted? How do I report changes to the labeling materials since the last report?	514.80(b)(4)(ii) Labeling.
	514.80(b)(4)(iii) Nonclinical laboratory studies and clinical data not previously reported.
What are the requirements for submission of nonclinical laboratory studies?	514.80(b)(4)(iii)(A).
What are the requirements for submission of clinical laboratory data?	514.80(b)(4)(iii)(B).
When must results of clinical trials conducted by or for the applicant be reported?	514.80(b)(4)(iii)(C).
	514.80(b)(4)(iv) Adverse drug experiences.
How do I report product/manufacturing defects and adverse drug experiences not previously reported to FDA?	514.80(b)(4)(iv)(A).
What are the requirements for submitting adverse drug experiences cited in literature?	514.80(b)(4)(iv)(B).
What are the requirements for submitting adverse drug experiences in postapproval studies and clinical trials?	514.80(b)(4)(iv)(C).
What are the requirements for reporting increases in the frequency of serious, expected, and unexpected adverse drug experiences?	514.80(b)(4)(v) Summary report of increased frequency of adverse drug experience.
	514.80(b)(5) Other reporting.
Can FDA request that an applicant submit information at different times than stated specifically in this regulation?	514.80(b)(5)(i) Special drug experience report.
What are the requirements for submission of advertisement and promotional labeling to FDA?	514.80(b)(5)(ii) Advertisements and promotional labeling.
What are the requirements for adding a new distributor to the approved application?	514.80(b)(5)(iii) Distributor's statement.
What labels and how many labels need to be submitted for review?	514.80(b)(5)(iii)(A).
What changes are required and allowed to distributor labeling?	514.80(b)(5)(iii)(A)(1).
What are the requirements for making other changes to the distributor labeling?	514.80(b)(5)(iii)(A)(2).
What information should be included in each new distributor's signed statement?	514.80(b)(5)(iii)(B)(1) through (b)(5)(iii)(B)(5).
What are the conditions for submitting information that is common to more than one application? (i.e., can I submit common information to one application?)	514.80(c) Multiple applications.
What information has to be submitted to the common application and related application?	514.80(c)(1) through (c)(4).