



Postmarketing Surveillance of Generic Drugs



Once a generic medication is available for prescription or over-the-counter use, FDA continues to monitor its safety, efficacy, and quality.



After FDA approval, generic drug manufacturers must report any problems or serious adverse health effects to FDA for evaluation.



FDA periodically inspects manufacturing plants and continues to monitor drug quality.



Generic drug manufacturers will often propose changes to their products after they are approved; FDA evaluates these changes to ensure the drugs are still safe and effective.



FDA monitors FAERS (the FDA Adverse Event Reporting System) and reviews MedWatch reports to investigate concerns related to generic drug product quality and therapeutic inequivalence.

Visit www.FDA.gov/GenericDrugs
to learn more.



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