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The Drug Development and Approval Process

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This brief summary of the drug development process is provided to help define the origins of different names used to identify drugs. Drugs intended for clinical use undergo several phases of development before they can be considered for human use. Animal studies are performed initially to assess pharmacologic and toxicologic effects. While clinical studies are being conducted, animal studies may continue to assess effects on reproduction, teratogenicity, and carcinogenicity.(p63) To perform clinical studies in the United States, the developer or manufacturer must obtain an investigational new drug (IND) approval from the US Food and Drug Administration (FDA).(p59) Once an IND