TABLE 1–1 American Drug Laws and Amendments

Year	Name	Main Provision(s)
1906	Pure Food and Drug Act	Established official standards and requirements for accurate labeling of drug products
1912	Sherley Amendment	Prohibited fraudulent claims of drug effectiveness
1914	Harrison Narcotic Act	Restricted the importation, manufacture, sale, and use of opium, cocaine, marijuana, and other drugs that the act defined as narcotics
1938	Food, Drug, and Cosmetic Act	• Required proof of safety from the manufacturer before a new drug could be marketed • Authorized factory inspections • Established penalties for fraudulent claims and misleading labels
1945	Amendment	Required governmental certification of biologic products, such as insulin and antibiotics
1952	Durham-Humphrey Amendment	Designated drugs that must be prescribed by a physician and dispensed by a pharmacist (eg, controlled substances, drugs considered unsafe for use except under supervision by a health care provider, and drugs limited to prescription use under a manufacturer's new drug application)
1962	Kefauver-Harris Amendment	• Required a manufacturer to provide evidence (from well-controlled research studies) that a drug was effective for claims and conditions identified in the product's labeling • Gave the federal government the authority to standardize drug names
1970	Comprehensive Drug Abuse Prevention and Control Act; Title II, Controlled Substances Act	• Regulated distribution of narcotics and other drugs of abuse • Categorized these drugs according to therapeutic usefulness and potential for abuse
1978	Drug Regulation Reform Act	• Established guidelines for research studies and data to be submitted to the FDA by manufacturers • Shortened the time required to develop and market new drugs
1983	Orphan Drug Act	• Decreased taxes and competition for manufacturers who would produce drugs to treat selected serious disorders affecting relatively few people
1987		• Established new regulations designed to speed up the approval process for high-priority medications
1992	Prescription Drug User Fee Act	• Allowed the FDA to collect user fees from pharmaceutical companies, with each new drug application, to shorten the review time (eg, by hiring more staff) • Specified a review time of 12 months for standard drugs and 6 months for priority drugs
1997	FDA Modernization Act	• Updated regulation of biologic products • Increased client access to experimental drugs and medical devices • Accelerated review of important new drugs • Allowed drug companies to disseminate information about off-label (non–FDA-approved) uses and costs of drugs • Extended user fees

FDA, Food and Drug Administration.

BOX 1–1 CATEGORIES OF CONTROLLED SUBSTANCES

Schedule I
Drugs that are not approved for medical use and have high abuse potentials: heroin, lysergic acid diethylamide (LSD), peyote, mescaline, tetrahydrocannabinol, marijuana.

Schedule II
Drugs that are used medically and have high abuse potentials: opioid analgesics (eg, codeine, hydromorphone, methadone, meperidine, morphine, oxycodone, oxymorphone), central nervous system (CNS) stimulants (eg, cocaine, methamphetamine, methylphenidate), and barbiturate sedative-hypnotics (amobarbital, pentobarbital, secobarbital).

Schedule III
Drugs with less potential for abuse than those in Schedules I and II, but abuse may lead to psychological or physical dependence: androgens and anabolic steroids, some CNS stimulants (eg, benzphetamine), and mixtures containing small amounts of controlled substances (eg, codeine, barbiturates not listed in other schedules).

Schedule IV
Drugs with some potential for abuse: benzodiazepines (eg, diazepam, lorazepam, temazepam), other sedative-hypnotics (eg, phenobarbital, chloral hydrate), and some prescription appetite suppressants (eg, mazindol, phentermine).

Schedule V
Products containing moderate amounts of controlled substances. They may be dispensed by the pharmacist without a physician's prescription but with some restrictions regarding amount, record keeping, and other safeguards. Included are antidiarrheal drugs, such as diphenoxylate and atropine (Lomotil).