

<i>Generic Name</i>	<i>Brand Name (Company)</i>	<i>Indication</i>	<i>Dosage Form (Date)</i>
New Dosage Forms/Strengths			
Amoxicillin/ clavulanate potassium	Augmentin XR (GlaxoSmithKline)	Treatment of adults with acute bacterial sinusitis (ABS) or community-acquired pneumonia (CAP)	Tablet (9/02)
Methylphenidate	Ritalin LA (Novartis)	Once daily formulation	Capsule (8/02)
Norgestimate/ Ethinyl estradiol	Ortho Tri-Cyclen Lo (Ortho-McNeil)	Ethinyl estradiol 25 mcg x 21 days Norgestimate 180 mcg daily (days 1 to 7); 215 mcg daily (days 8 to 14); 250 mcg daily (days 15 to 21)	Tablet (8/02)
New Indications			
Repaglinide	Prandin (Novo Nordisk)	Combination therapy with rosiglitazone or pioglitazone for the treatment of type 2 diabetes	10/02
Anastrozole	Arimidex (AstraZeneca)	Adjuvant treatment of hormone-receptor positive early stage breast cancer in postmenopausal women	Tablet (9/02)
Escitalopram oxalate	Lexapro (Forest Laboratories)	Maintenance treatment for patients with major depressive disorder	Tablet (8/02)
Granisetron	Kytril (Roche)	Prevention and treatment of postoperative nausea and vomiting	Injection (8/02)
Irbesartan	Avapro (Bristol Myers Squibb)	Treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria (urinary albumin to creatinine ratio = 300 mg/g) in patients with type 2 diabetes and a history of hypertension	Tablet (9/02)
Lansoprazole	Prevacid (TAP)	Pediatric use for short-term treatment of symptomatic GERD and erosive esophagitis in children 1 to 11 years of age	Tablet, oral suspension, capsule (8/02)
Losartan	Cosart (Merck)	Treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria (urinary albumin to creatinine ratio = 300 mg/g) in patients with type 2 diabetes and a history of hypertension	Tablet (9/02)
Valacyclovir	Valtrex (GlaxoSmithKline)	Treatment of cold sores in healthy adults using a one day dose	Tablet (9/02)
Valsartan	Diovan (Novartis)	Treatment of heart failure in patients who are intolerant of angiotensin-converting-enzyme (ACE) inhibitors	Tablet (8/02)

New Drugs Pending Legislation

Puja Mehta



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New Drugs American Enterprise Institute for Public Policy Research,1976 **A Legislative History of the Federal Food, Drug, and Cosmetic Act and Its Amendments** United States,1979 *Drug Regulation Reform Act of 1978* United States. Congress. House. Committee on Interstate and Foreign Commerce. Subcommittee on Health and the Environment,1979 *A Legislative History of the Federal Food, Drug, and Cosmetic Act and Its Amendments* ,1979 **The Textbook of Pharmaceutical Medicine** John P. Griffin,John Posner,Geoffrey R. Barker,2013-03-29 The Textbook of Pharmaceutical Medicine is the standard reference for everyone working and learning in pharmaceutical medicine It is a comprehensive resource covering the processes and practices by which medicines are developed tested and approved and the recognised text for the Diploma in Pharmaceutical Medicine from the Faculty of Pharmaceutical Medicine This fully revised Seventh Edition which includes two new Editors encompasses current developments within pharmaceutical medicine with new chapters on biological therapeutics pharmacovigilance vaccines drugs for cancer drug development in paediatrics and neonatology the clinical trials directive life cycle management of medicines counterfeit medicines and medical marketing Also included for easy reference and referred to throughout the text are the Declaration of Helsinki Guidelines and Documentation for Implementation of Clinical Trials relevant European Directives and the Syllabus for Pharmaceutical Medicine Written by an international team of leading academics medical directors and lawyers The Textbook of Pharmaceutical Medicine Seventh Edition meets the needs of both those working in pharmaceutical medicine and preparing for the Diploma in Pharmaceutical Medicine The text breaks down into three core sections Part I Research and Development Part II Regulation Part III Healthcare marketplace View Table of Contents in detail *Use of Advisory Committees by the Food and Drug Administration* United States. Congress. House. Committee on Government Operations. Intergovernmental Relations Subcommittee,1975 **Drug Industry Act of 1962** United States. Congress. House. Committee on Interstate and Foreign Commerce,1962 Considers the following bills to amend the Federal Food Drug and Cosmetic Act H R 11581 the Drug and Factory Inspection Amendments of 1962 to require manufacturers to follow certain research production and marketing safety procedures H R 11582 the Cosmetics and Therapeutic Devices Amendments of 1962 to require safety certification for cosmetics and medical devices to require labeling on containers containing hazardous substances and to strengthen controls on food and animal feed additives **Drug Industry Act of 1962, Hearings ... 87-2 ... June 19, 20, 21, 22, August 20, 21, 22, 23, 1962** United States. Congress. House. Interstate and Foreign Commerce,1962 *Drug Abuse Control Amendments-1970, Hearings Before the Subcommittee on Public Health and Welfare ... on H.R. 11701 and H.R. 13743* United States. Congress. House Interstate and Foreign Commerce,1970 *Federal Register* ,1980-12-09

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