

FDA Approvals of New Drug Applications (NDAs) for New Molecular Entities and New Active Ingredients¹
January 1994 – December 1998

Date of Approval	Drug Name	Active Ingredient	Prodrug?	Prodrug Type (if applicable)
02/04/1994	Serevent	Salmeterol xinafoate	No	n/a
02/14/1994	Rhinocort	Budesonide	No	n/a
03/17/1994	Zemuron	Rocuronium bromide	No	n/a
03/25/1994	Semprex-D	Acrivastine; pseudoephedrine hydrochloride	No	n/a
03/25/1994	lobenguane Sulfate I 131	lobenguane sulfate I-131	No	n/a
04/08/1994	Prograf	Tacrolimus	No	n/a
05/23/1994	Cerezyme	Imiglucerase	No	n/a
06/02/1994	OctreoScan	Indium in-111 pentetreotide kit	No	n/a
06/24/1994	Zerit	Stavudine	No	n/a
06/29/1994	Famvir	Famciclovir	Yes	Diacetyl ester
08/15/1994	Cystagon	Cysteamine bitartrate	No	n/a
08/19/1994	Fludeoxyglucose F 18	Fludeoxyglucose f-18	No	n/a
11/23/1994	Neurilite	Technetium tc-99m bicasate kit	No	n/a
12/05/1994	Luvox	Fluvoxamine maleate	No	n/a
12/09/1994	Trusopt	Dorzolamide hydrochloride	No	n/a
12/22/1994	Serzone	Nefazodone hydrochloride	No	n/a
12/22/1994	Fragmin	Dalteparin sodium	No	n/a
12/23/1994	Navelbine	Vinorelbine tartrate	No	n/a
12/27/1994	Lamictal	Lamotrigine	No	n/a

¹ This chart was compiled using the database of approved drugs available at the FDA website. *Drugs@FDA: FDA Approved Drug Products*, FDA, <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Reports.ReportsMenu> (last visited Mar. 15, 2015).

Date of Approval	Drug Name	Active Ingredient	Prodrug?	Prodrug Type (if applicable)
12/29/1994	Renormax	Spirapril hydrochloride	Yes	Mono ethyl ester of a dicarboxylic acid
12/30/1994	Vexol	Rimexolone	No	n/a
02/02/1995	Sular	Nisoldipine	No	n/a
03/03/1995	<i>Ultram</i> ²	<i>Tramadol hydrochloride</i>	No	<i>n/a</i>
03/03/1995	Glucophage	Metformin hydrochloride	No	n/a
03/31/1995	Betimol	Timolol	No	
04/14/1995	<i>Cozaar</i>	<i>Losartan potassium</i>	No	<i>n/a</i>
04/17/1995	Revex	Nalmefene hydrochloride	No	n/a
04/19/1995	Univasc	Moexipril hydrochloride	Yes	Mono ethyl ester of a dicarboxylic acid
05/03/1995	Cellcept	Mycophenolate mofetil	Yes	<i>N</i> -ethoxy morpholine ester
05/10/1995	Ultravist 150	lopromide	No	n/a
05/10/1995	Ultravist 240	lopromide	No	n/a
05/10/1995	Ultravist 300	lopromide	No	n/a
05/10/1995	Ultravist 300 in Plastic Container	lopromide	No	n/a
05/10/1995	Ultravist 370	lopromide	No	n/a
05/26/1995	Zinecard	Dexrazoxane hydrochloride	No	n/a
06/07/1995	Ultane	Sevoflurane	No	n/a
06/19/1995	Dynabac	Dirithromycin	Yes	Aminal prodrug; spontaneous hydrolysis in plasma
06/23/1995	Valtrex	Valacyclovir hydrochloride	Yes	Valine ester promoiety
09/06/1995	Precose	Acarbose	No	n/a
09/13/1995	Azelex	Azelaic acid	No	n/a
09/14/1995	Coreg	Carvedilol	No	n/a
09/18/1995	Bactroban	Mupirocin calcium	No	n/a

² Italicized entries have metabolites that contribute to the pharmacology of the drug.

Date of Approval	Drug Name	Active Ingredient	Prodrug?	Prodrug Type (if applicable)
09/20/1995	Flolan	Epoprostenol sodium	No	n/a
09/29/1995	Fosamax	Alendronate sodium	No	n/a
10/04/1995	Casodex	Bicalutamide	No	n/a
11/17/1995	Epivir	Lamivudine	No	n/a
11/20/1995	Abelcet	Amphotericin b	No	n/a
11/30/1995	Amaryl	Glimepiride	No	n/a
12/06/1995	Invirase	Saquinavir mesylate	No	n/a
12/08/1995	Zyrtec Allergy	Cetirizine hydrochloride	No	n/a
12/08/1995	Zyrtec Hives Relief	Cetirizine hydrochloride	No	n/a
12/08/1995	Ethylol	Amifostine	Yes	Thiophosphate prodrug
12/12/1995	Rilutek	Riluzole	No	n/a
12/15/1995	Nimbex	Cisatracurium besylate	No	n/a
12/15/1995	Nimbex Preservative Free	Cisatracurium besylate	No	n/a
12/20/1995	Cedax	Ceftibuten dihydrate	No	n/a
12/21/1995	Oxilan-300	loxilan	No	n/a
12/21/1995	Oxilan-350	loxilan	No	n/a
12/27/1995	Photofrin	Porfimer sodium	No	n/a
12/27/1995	Arimidex	Anastrozole	No	n/a
12/28/1995	Corvert	Ibutilide fumarate	No	n/a
01/18/1996	Maxipime	Cefepime hydrochloride	No	n/a
02/09/1996	Myoview	Technetium tc-99m tetrofosmin kit	No	n/a
02/09/1996	Myoview 30 mL	Technetium tc-99m tetrofosmin kit	No	n/a

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03/01/1996	Norvir	Ritonavir	No	n/a
03/13/1996	Crixivan	Indinavir sulfate	No	n/a
03/22/1996	Visipaque 270	Iodixanol	No	n/a
03/22/1996	Visipaque320	Iodixanol	No	n/a
04/26/1996	Mavik	Trandolapril	Yes	Mono ethyl ester of a dicarboxylic acid
04/30/1996	Buphenyl	Sodium phenylbutyrate	No	n/a
05/14/1996	Taxotere	Docetaxel	No	n/a
05/15/1996	Gemzar	Gemcitabine hydrochloride	No	n/a
05/17/1996	Etopophos Preservative Free	Etoposide phosphate	Yes	Phosphate prodrug
05/23/1996	Achrel	Corticoreslin ovine trifluate	No	n/a
05/28/1996	Hycamtin	Topotecan hydrochloride	No	n/a
05/31/1996	Differin	Adapalene	No	n/a
06/05/1996	Xalatan	Latanoprost	Yes	Isopropyl alcohol ester of a carboxylic acid

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06/11/1996	Albenza	Albendazole	No	n/a
06/14/1996	Remeron	Mirtazapine	No	n/a
06/14/1996	Humalog	Insulin lispro recombinant	No	n/a
06/14/1996	Humalog Kwikpen	Insulin lispro recombinant	No	n/a
06/14/1996	Humalog Pen	Insulin lispro recombinant	No	n/a
06/14/1996	Camptosar	Irinotecan hydrochloride	Yes	Carbamate prodrug of a phenol
06/21/1996	Viramune	Nevirapine	No	n/a
06/21/1996	Merrem	Meropenem	No	n/a
06/26/1996	Vistide	Cidofovir	No	n/a
07/12/1996	Ultiva	Remifentanyl hydrochloride	No	n/a
07/25/1996	Allegra	Fexofenadine hydrochloride	No	n/a
08/05/1996	Cerebyx	Fosphenytoin sodium	Yes	Phosphate prodrug with a spacer
08/26/1996	Ivy Block	Bentoquatam	No	n/a
08/30/1996	Feridex I.V.	Ferumoxides	No	n/a
09/06/1996	ProAmatine	Midodrine hydrochloride	Yes	Glycine amide prodrug of an amine
09/06/1996	Alphagan	Brimonidine tartrate	No	n/a
09/17/1996	Breathek UBT for H-Pylori	Urea c-13	No	n/a
09/17/1996	Meretek UBT Kit (w/ Pranaactin)	Urea c-13	No	n/a
09/19/1996	Nilandron	Nilutamide	No	n/a
09/24/1996	Naropin	Ropivacaine hydrochloride	No	n/a
09/24/1996	Denavir	Penciclovir sodium	No	n/a
09/26/1996	Elmiron	Pentosan polysulfate sodium	No	n/a
09/26/1996	Accolate	Zafirlukast	No	n/a
09/30/1996	Zyprexa	Olanzapine	No	n/a

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