1994 FDA Drug Approval

During 1994 the FDA approved 62 drugs and 23 biological products, including 22 new molecular entities [NME's] (18 drugs and 4 diagnostics). Since Congress approved an accelerated approval process for the FDA in 1992, which allocated new funding to hire additional FDA review staff through a user-fee program, the time drugs are in the approval process has decreased 20% to 50%. Major approvals are listed in four tables. (Discontinuances or "approvables" are not listed.)

THE FDA EVALUATION CODES INDICATING PRESENCE OR ABSENCE OF THERAPEUTIC EQUIVALENCY

PRINCIPLE CATEGORIES

- A Drug products that are considered to be therapeutically equivalent to other pharmaceutically equivalent products.
- B Drug products not considered at this time to be therapeutically equivalent to other pharmaceutically available products.

SUBGROUPS OF "A" RATED PRODUCTS

(considered to be therapeutically equivalent)

- AA Products in conventional dosage forms (tablets, capsules, liquids) not presenting bioequivalence problems.
- AB Products meeting necessary bioequivalence requirements whose actual or potential bioequivalence problems have been resolved through appropriate scientific testing.
- AN Bioequivalent solutions & powders for aerosolization.
- AO Bioequivalent injectable oil solutions.
- AP Bioequivalent injectable equeous solutions.
- AT Bioequivalent topical products.

SUBGROUPS OF "B" RATED PRODUCTS

(considered not to be therapeutically equivalent)
Actual or potential bioequivalence problems have not yet been resolved through reformulation and appropriate scientific testing.

- BC Extended release dosage forms (tablets, capsules, injectables).
- BD Documented bioequivalence problems with active ingredients and dosage forms.
- BE Delayed release oral dosage forms.
- BN Products in aerosol-nebulizer delivery system.
- BP Potential bioequivalence problems with active ingredients and dosage forms.
- BR Suppositories or enemas that deliver drugs for system absorption.
- BS Products having drug-standard deficiencies.
- BT Topical products with bioequivalence issues.
- BX Drug products for which the data are insufficient to determine therapeutic equivalency.

GENERIC NAME	TRADE NAME • COMPANY	INDICATION	FDA RATING*
	NEW MOLECULAR ENTITIES		
abciximab	ReoPro/ Centocor-Lilly	platelet aggregation inhibitor	1P
acrivastine & pseudoephedrine	Semprex-D/ Burroughs Wellcome	allergy relief	1S
cysteamine bitartrate	Cystagon/ Mylan	nephropathic cystinosis	1P
dalteparin sodium	Fragmin/ Pharmacia	prevention of deep vein thrombosis	1S
dorzolamide	Trusopt/ Merck	ocular hypertension & glaucoma	1P
famciclovir	Farnvir/ SKB	acute herpes zoster	1S
fluvoxamine	Luvox/ Solvay	obsessive-compulsive	1S
budesonide	Rhinocort/Astra	allergy symptoms	1S
imiglucerase	Cerezyme/ Genzyme	Gaucher's disease	1P
lamotrigine	Lamictal/ Burroughs Wellcome	epilepsy	1S
metformin	Glucophage/ BMS	NIDDM	1P
nefazodone	Serzone/ BMS	depression	1S
rimexolone	Vexol/ Alcon	postoperative inflammation after cataract surgery	1P
rocuronium	Zemuron/ Organon	neuromuscular blocking agent	1S
salmeterol xinafoate	Serevent/ Glaxo	prevention of bronchospasm	1P
spirapril	Renormax/ Sandoz	hypertension	1S
stavudine	Zerit/ BMS	advanced HIV disease	1P
tacrolimus	Prograf/ Fujisawa	prevention of transplant graft	1P
vinorelbine tartrate	Navelbine/ Burroughs Wellcome	non-small cell lung cancer	1P

*1: A new molecular entity; S: Drug with therapeutic qualities similar to products currently on the market; P: Drug represents a therapeutic advance over products currently on the market

GENERIC NAME	TRADE NAME • CO.	FDA RATING
	DIAGNOSTICS	
f-18 injection	Fludeoxyglucose/ Downstate Clinical	1P
m-idobenzyl guanidine sulfate	Lobenguane sulfate	1P
technetium 99m bicisate	Neurolite/ DuPont Merck	1S
indium-111 pentetreotide	Octreo Scan/ Mallinkrodt	1P
	OTHER APPROVALS	
clorpheniramine 24 hr.	Efidac 24 chlorpheniramine/ Ciba	
glipizide GITS	Glucotrol XL/ Alza Pfizer	
loratadine/pseudoephredrine	Claritin-D/Schering-Plough	
pentamidine iscthionate	Pentacarinat/ Rhone-Poulenc Rorer	
pegaspargase	Oncaspar/ Rhone-Poulenc Rorer	
rifampin & isoniazid	Rifater/ MMD	

GENERIC NAME	GENERIC CO.	TRADE NAME • CO.
	GENERIC PRODUCT APPROVALS	
cefaclor	Mylan	Ceclor/ Lilly
cimetidine	Lilly	Tagamet/ SKB
clobestasol propionate	Copley	Temovate/Glaxo
diltiazem	Prographarm	Cardizem SR/ MMD
etoposide	Gensia	VePesid/ BMS
guanabenz acetate	Watson	Wytensive/ Wyete Ayerst
levobunolol	Bausch & Lomb	Betagan/ Allergan
lithium carbonate	Solvay	Lithobid/ Ciba
miconazole	Able	Monistat 7/ Ortho
phenylpropanolamine/ clemastine forarate	Perrigo	Tavist-D/ Sandoz
prochlorperazine	G&W	Compazine/ SKB
quinidine sulfate sustained release	Copley	Quinidep Extentabs/ Robins