New and Generic Drug Approvals

December 4, 2012

Drug Name	Active Ingredient	Dosage Form/Route	Sponsor	Submission Type
Candesartan Cilexetil and Hydrochlorothiazide	candesartan cilexetil; hydrochlorothiazide	Tablet; Oral	Mylan Labs	Approval
Candesartan Cilexetil and Hydrochlorothiazide	candesartan cilexetil; hydrochlorothiazide	Tablet; Oral	Apotex Inc	Approval
Enbrel	etanercept	Syringe	Immunex	Labeling Revision
Enbrel	etanercept	Vial; Subcutaneous	Immunex	Labeling Revision
Infuvite Adult	alpha-tocopherol acetate; ascorbic acid; biotin; cholecalciferol; cyanocobalamin; dexpanthenol; folic acid; niacinamide; pyridoxine hydrochloride; riboflavin 5-phosphate sodium; thiamine hydrochloride; vitamin a palmitate; vitamin k	Injectable; IV (Infusion)	Sandoz	Labeling Revision
Motrin IB	ibuprofen	Tablet; Oral	Mcneil	Manufacturing Change or Addition
Motrin Migraine Pain	ibuprofen	Tablet; Oral	Mcneil	Manufacturing Change or Addition
Nizoral	ketoconazole	Shampoo; Topical	Janssen Pharms	Labeling Revision
Nuprin	ibuprofen	Tablet; Oral	Mcneil	Manufacturing Change or Addition
Omontys	peginesatide acetate	Solution; Intravenous, Subcutaneous	Affymax	Labeling Revision
Omontys Preservative Free	peginesatide acetate	Solution; Intravenous,	Affymax	Labeling Revision

		Subcutaneous		
Zanosar	streptozocin	Injectable; Injection	Teva Parenteral	Manufacturing Change or Addition

December 3, 2012

Drug Name	Active Ingredient	Dosage Form/Route	Sponsor	Submission Type
Celexa	citalopram hydrobromide	Tablet; Oral	Forest Labs	Labeling Revision
Celexa	citalopram hydrobromide	Solution; Oral	Forest Labs	Labeling Revision
Humulin N	insulin susp isophane recombinant human	Injectable; Injection	Lilly	Manufacturing Change or Addition
Lexapro	escitalopram oxalate	Tablet; Oral	Forest Labs	Labeling Revision
Lexapro	escitalopram oxalate	Solution; Oral	Forest Labs	Labeling Revision
Restasis	cyclosporine	Emulsion; Ophthalmic	Allergan	Labeling Revision
Surmontil	trimipramine maleate	Capsule; Oral	Odyssey Pharms	Labeling Revision
Victoza	liraglutide recombinant	Solution; Subcutaneous	Novo Nordisk Inc	Manufacturing Change or Addition
Vimpat	lacosamide	Tablet; Oral	UCB Inc	Manufacturing Change or Addition

December 7, 2012

Drug Name	Active Ingredient	Dosage Form/Route	Sponsor	Submission Type
Diltiazem Hydrochloride	diltiazem hydrochloride	Capsule, Extended Release; Oral	Actavis Inc	Approval
Fenofibrate	fenofibrate	Tablet; Oral	Mylan	Approval

			Pharms Inc	