CDER Drug and Biologic Approvals for Calendar Year 2009

Updated through June 30, 2009

New Drug Application (NDA) Approvals:

Application Type	Application Number	Proprietary Name	Established Name	Applicant	Chemical Type	Review Classification	505B2 FLAG	Approval Date
N	022256	SAVELLA	MILNACIPRAN HYDROCHLORIDE	CYPRESS BIOSCIENCE	1	S		14-Jan-09
N	022087	VERTICAL	CALCITRIOL	GALDERMA	3	S		23-Jan-09
N	022204	GELNIQUE	OXYBUTYNIN CHLORIDE	WATSON	3	S		27-Jan-09
N	022287	KAPIDEX	DEXLANSOPRAZOLE	TAKEDA	2	S		30-Jan-09
N	021856	ULORIC	FEBUXOSTAT	TAKEDA	1	S		13-Feb-09
N	050818	TOBRADEX ST	TOBAMYCIN/ DEXAMETHASONE	ALCON	3	S	Y	13-Feb-09
N	022370*	TRAMADOL HYDROCHLORIDE	TRAMADOL HYDROCHLORIDE	CIPHER	3	S	Y	13-Feb-09
N	022278	MEMBRANEBLUE	TRYPAN BLUE	DORC INTERNATIONAL	5	P		20-Feb-09
N	022277	TEMODAR	TEMOZOLOMIDE	SCHERING	3	S		27-Feb-09
N	021997	ZOLPIDEM TARTRATE	ZOLPIDEM TARTRATE	OREXO AB	3	S	Y	13-Mar-09
N	022347*	STAVUDINE/LAMIVUDINE	30MG/150MG & 40MG/150MG TAB	PHARMACARE LTD	4	S		18-Mar-09
N	022334	AFFINITOR	EVEROLIMUS	NOVARTIS	1	P		30-Mar-09
N	022268	COARTEM	ARTEMETHER/ LUMEFANTRINE	NOVARTIS	1	P,O		07-Apr-09
N	022129	PHYXXLICE	BENZYL ALCOHOL	SCIELE PHARMA	1	S		09-Apr-09
N	022154	TYZEKA	TELBIVUDINE	NOVARTIS	3	S		28-Apr-09
N	020725	CREON	PANCRELIPASE	SOLVAY	7	P		30-Apr-09
N	022314	EXFORGE HCT	AMLODIPINE/VALSARTAN/HYDROCHLOROTHIAZIDE	NOVARTIS	4	S	Y	30-Apr-09
N	021918	CETRAXAL	CIPROFLOXACIN OTIC SOLUTION	LABORATORIOS SALVAT	3	S	Y	01-May-09
N	020866	CYCLOSET	BROMOCRIPTINE MESYLATE	VEROSCIENCE	3	S	Y	05-May-09

N	022192	FANAPT	ILOPERIDONE	VANDA PHARMS INC	1	S		06-May-09
N	022251	LAMICTAL ODT	LAMOTRIGINE	SMITHKLINE BEECHAM	3	S		08-May-09
N	022024	ACTOPLUS MET XR	PIOGLITAZONE HYDROCHLORIDE/METFORMIN HYDROCHLORIDE	TAKEDA GLOBAL	3	S		12-May-09
N	022327	PREVACID 24 HR	LANSOPRAZOLE	NOVARTIS CONS	5	S		18-May-09
N	022360	NICORETTE	NICOTINE POLACRILEX	GLAXOSMITHKLINE CONS	5	S		18-May-09
N	022275	SAMSCA	TOLVAPTAN	OTSUKA AMERICA PHARM	1	S		19-May-09
N	022160*	OXALIPLATIN INJECTION	OXALIPLATIN INJECTION	TEVA PARENTERAL	5	S		22-May-09
N	022308	BESIVANCE	BESIFLOXACIN	BAUSCH AND LOMB	1	S		28-May-09
N	022115	LAMICTAL XR	LAMOTRIGINE	SMITHKLINE BEECHAM	3	S		29-May-09
N	022348	CALDOLOR	IBUPROFEN	CUMBERLAND PHARMS	5	P	Y	11-Jun-09
N	022202	ZIPSOR	DICLOFENAC POTASSIUM	XANODYNE PHARMS INC	3	S	Y	16-Jun-09
N	022165	CAMBIA	DICLOFENAC	PROETHIC PHARMS	3	S	Y	17-Jun-09
N	022315	OZURDEX	DEXAMETHASONE INTRAVITREAL IMPLANT	ALLERGAN	3	P		17-Jun-09
N	022180	FERAHEME	FERUMOXYTOL	AMAG PHARMS INC	2	S		30-Jun-09

* NDA 22-370, TRAMADOL HYDROCHLORIDE, HAS BEEN TENTATIVELY APPROVED.

* NDA 22-347,STAVUDINE/LAMIVUDINE, HAS BEEN TENTATIVELY APPROVED.

* NDA 22-160, OXALIPLATIN, HAS BEEN TENTATIVELY APPROVED.

New Drug Application (NDA) Tentative Approvals under the President's Emergency Plan for AIDS Relief (PEPFAR):

Application Number	Proprietary Name	Established Name	Applicant	Chemical Type	Review Classification	505B2 FLAG	Approval Date
022346*	STAVUDINE/LAMIVUDINE/NEVIRAPINE	STAVUDINE/LAMIVUDINE/NEVIRAPINE	PHARMACARE	4	S	Y	27-Feb-09
022356*	LAMIVUDINE/ZIDOVUDINE/NEVIRAPINE	LAMIVUDINE/ZIDOVUDINE/NEVIRAPINE	HETERO DRUGS LTD	4	S		07-May-09

* NDA 22-346,STAVUDINE/LAMIVUDINE/NEVIRAPINE , HAS BEEN TENTATIVELY APPROVED UNDER PEPFAR.

* NDA 22-356, LAMIVUDINE/ZIDOVUDINE, HAS BEEN TENTATIVELY APPROVED UNDER PEPFAR.

Biologic License Application (BLA) Approvals:

BLA Number	Proprietary Name	Proper Name	Applicant	Review Classification	Approval Date
L 125289/0.0	GOLIMUMAB	SIMPONI	CENTOCOR ORTHO BIOTECH	S	24-Apr-09
L 125274/0.0	ABOBOTULINUMTOXIN A	DYSPORT	IPSEN BIOPHARM LIMITED	S	29-Apr-09
L 125319/0.0	CANAKINUMAB	ILARIS	NOVARTIS PHARMACEUTICALS CORPORATION	P	17-Jun-09

NDA Chemical Type:

1 - New molecular entity

2 - New ester, new salt, or other noncovalent derivative

3 - New dosage form

4 - New combination

5 - New formulation or new manufacturer

7 - Drug already marketed, but without an approved NDA

8 - OTC switch

Review Classification:

P - Priority Review - Significant improvement compared to marketed products, in the treatment, diagnosis, or prevention of a disease.

S - Standard Review - Products that do not qualify for priority review.

O - Orphan Designation - Pursuant to Section 526 of the Orphan Drug Act (Public Law 97-414 as amended).