



**CDER Drug and Biologic Calendar Year Priority Approvals
As of December 31, 2011**

Last Refresh Date: 1/6/2012

Selection Criteria:

User Response: Start Date: 1/1/2011 End Date: 12/31/2011

Sort Order: Approval Date

Application Number	Proprietary Name	Established Name	Applicant	Review Classification	Approval Date
NDA 022454	DATSCAN	IOFLUPANE 1-123 INJECTION	GE HEALTHCARE INC	P	1/14/2011
NDA 201444	NITHIODOTE	SODIUM NITRITE INJECTION AND SODIUM THIOSULFATE INJECTION	HOPE PHARMACEUTICALS	P,O	1/14/2011
NDA 022494	SODIUM FLUORIDE F-18	SODIUM FLUORIDE F-18	NATIONAL INSTITUTES HEALTH NATIONAL CANCER INSTITUTE DIV CANCER TREATMENT AND DIAGNOSIS	P	1/26/2011
NDA 021945	MAKENA	HYDROXYPREGESTERONE CAPROATE	HOLOGIC INC	P,O	2/3/2011
NDA 022405	VANDETANIB	VANDETANIB	IPR PHARMACEUTICALS INC	P,O	4/6/2011
NDA 202379	ZYTIGA	ABIRATERONE ACETATE	CENTOCOR ORTHO BIOTECH INC	P	4/28/2011
NDA 202007 (2)	ABACAVIR SULFATE AND LAMIVUDINE TABLETS	ABACAVIR SULFATE AND LAMIVUDINE TABLETS	CIPLA LTD	P	5/12/2011
NDA 202258	VICTRELIS™	BOCEPREVIR	SCHERING CORP	P	5/13/2011
NDA 201917	INCIVEK™	TELAPREVIR	VERTEX PHARMACEUTICALS INC	P	5/23/2011
NDA 201699	DIFICID	FIDAXOMICIN	OPTIMER PHARMACEUTICALS INC	P	5/27/2011
NDA 202080	OXECTA	OXYCODONE HCL	KING PHARMACEUTICALS RESEARCH DEVELOPMENT INC	P	6/17/2011
NDA 021359	RECTIV	NITROGLYCERIN	PROSTRAKAN INC	P	6/21/2011
NDA 202123	COMPLERA	EMTRICITABINE/RILPIVIRINE/TE NOFOVIR DISOPROXIL FUMARATE	GILEAD SCIENCES INC	P	8/10/2011
NDA 202429	ZELBORAF	VEMURAFENIB	HOFFMANN LA ROCHE INC	P,O	8/17/2011
NDA 022150	FIRAZYR	ICATIBANT ACETATE	SHIRE ORPHAN THERAPIES INC	P,O	8/25/2011
NDA 202570	XALKORI	CRIZOTINIB	PFIZER INC	P,O	8/26/2011
NDA 202192	JAKAFI	RUXOLITINIB	INCYTE CORP	P,O	11/16/2011
NDA 022282 (2)	ATAZANAVIR SULFATE AND RITONAVIR TABLETS	ATAZANAVIR SULFATE AND RITONAVIR TABLETS	MYLAN LABORATORIES LTD	P	11/18/2011
NDA 201655	OPANA ER	OXYMORPHONE HYDROCHLORIDE	ENDO PHARMACEUTICALS INC	P	12/9/2011
NDA 202895	PREZISTA	DARUNAVIR	TIBOTEC INC	P	12/16/2011
NDA 203045	ISENRESS	RALTEGRAVIR	MERCK SHARP AND DOHME CORP	P	12/21/2011

Biologic License Application (BLA) Approvals:

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE
L 125370/0.0	BENLYSTA	BELIMUMAB	HUMAN GENOME SCIENCES, INC.	P	3/9/2011
L 125377/0.0	YERVOY	IPILIMUMAB	BRISTOL-MYERS SQUIBB COMPANY	P,O	3/25/2011
L 125388/0.0	ADCETRIS	BRENTUXIMAB VEDOTIN	SEATTLE GENETICS, INC.	P,O	8/19/2011
L 125359/0.0	ERWINAZE	ASPARAGINASE ERWINIA CHRYSANTHEMI	EUSA PHARMA (USA) INC..	P,O	11/18/2011
L 125387/0.0	EYLEA	AFLIBERCEPT	REGENERON PHARMACEUTICALS, INC.	P	11/18/2011

(1) Application has been tentatively approved.

(2) Application has been tentatively approved or approved under PEPFAR.

Review Classification:

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

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