

CY 2015 CDER Drug and Biologic Calendar Year Priority Approvals As of December 31, 2015

This report reflects the data shown as it is identified in the database.

Selection Criteria:

User Response: Start Date: 1/1/2015 End Date: 12/31/2015

Sort Order: Approval Date

APPLICATION NUMBER	PROPRIETARY NAME	ESTABLISHED NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE
NDA 206276	PAZEO	OLOPATADINE HYDROCHLORIDE	ALCON RESEARCH LTD	P	1/30/2015
NDA 207103	IBRANCE	PALBOCICLIB	PFIZER INC	P	2/3/2015
NDA 206947	LENVIMA	LENVATINIB	EISAI INC	P,O	2/13/2015
NDA 205353	FARYDAK	PANOBINOSTAT	NOVARTIS PHARMACEUTICALS CORP	P,O	2/23/2015
NDA 206494	AVYCAZ	CEFTAZIDIME-AVIBACTAM	CEREXA INC	P	2/25/2015
NDA 207500	CRESEMBA	ISAVUCONAZONIUM SULFATE	ASTELLAS PHARMA US INC	P,O	3/6/2015
NDA 207501	CRESEMBA	ISAVUCONAZONIUM SULFATE	ASTELLAS PHARMA US INC	P,O	3/6/2015
NDA 205750	CHOLBAM	CHOLIC ACID	ASKLEPION PHARMACEUTICALS LLC	P,O	3/17/2015
NDA 207925	KALYDECO	IVACAFTOR	VERTEX PHARMACEUTICALS INC	P,O	3/17/2015
NDA 205040 (2)		RITONAVIR TABLETS 25MG AND RITONAVIR TABLETS 50MG	CIPLA LTD	P	3/29/2015
NDA 206143	CORLANOR	IVABRADINE	AMGEN INC	P	4/15/2015
NDA 207946	INVEGA TRINZA	PALIPERIDONE PALMITATE	JANSSEN PHARMACEUTICALS INC	P	5/18/2015
NDA 205425 (2)		LOPINAVIR AND RITONAVIR	CIPLA LTD	P	5/21/2015
NDA 206940	VIBERZI	ELUXADOLINE	FURIEX PHARMACEUTICALS INC	P	5/27/2015
NDA 206038	ORKAMBI	LUMACFTOR/IVACAFTOR	VERTEX PHARMACEUTICALS INC	P,O	7/2/2015
NDA 207620	ENTRESTO	SACUBITRIL/VALSARTAN	NOVARTIS PHARMACEUTICALS CORP	P	7/7/2015
NDA 206843	DAKLINZA	DACLATASVIR	BRISTOL-MYERS SQUIBB CO	P	7/24/2015
NDA 207931	TECHNIVIE	OMBITASVIR, PARITAPREVIR, AND RITONAVIR	ABBVIE INC	P	7/24/2015
NDA 207027	PROMACTA	ELTROMBOPAG	NOVARTIS PHARMACEUTICALS CORP	P,O	8/24/2015
NDA 208169	XURIDEN	URIDINE TRIACETATE	WELLSTAT THERAPEUTICS CORP	P,O	9/4/2015
NDA 207793	ONIVYDE	IRINOTECAN LIPOSOME INJECTION	MERRIMACK PHARMACEUTICALS INC	P,O	10/22/2015
NDA 207953	YONDELIS	TRABECTEDIN	JANSSEN PRODUCTS LP	P,O	10/23/2015
NDA 206192	COTELLIC	COBIMETINIB	GENENTECH INC	P,O	11/10/2015
NDA 208065	TAGRISSO	OSIMERTINIB	ASTRAZENECA PHARMACEUTICALS LP	P,O	11/13/2015
NDA 208411	NARCAN NASAL SPRAY	NALOXONE HYDROCHLORIDE	ADAPT PHARMA INC	P	11/18/2015
NDA 208462	NINLARO	IXAZOMIB	MILLENNIUM PHARMACEUTICALS INC	P,O	11/20/2015
NDA 208159	VISTOGARD	URIDINE TRIACETATE	WELLSTAT THERAPEUTICS CORP	P,O	12/11/2015
NDA 208434	ALECENSA	ALECTINIB	HOFFMANN-LA ROCHE INC	P,O	12/11/2015
NDA 022225	BRIDION	SUGAMMADEX	ORGANON USA INC A SUBSIDIARY OF MERCK AND CO INC	P	12/15/2015
NDA 207865	EMEND	APREPITANT	MERCK SHARP AND DOHME CORP A SUBSIDIARY OF MERCK AND CO INC	P	12/17/2015

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE
BLA 125516/0.0	UNITUXIN	DINUTUXIMAB	UNITED THERAPEUTICS CORPORATION	P,O	3/10/2015
BLA 125559/0.0	PRALUENT	ALIROCUMAB	SANOFI-AVENTIS U.S. LLC	P	7/24/2015
BLA 761025/0.0	PRAXBIND	IDARUCIZUMAB	BOEHRINGER INGELHEIM PHARMACEUTICALS, INC	P	10/16/2015
BLA 125513/0.0	STRENSIQ	ASFOTASE ALFA	ALEXION PHARMACEUTICALS, INC.	P,O	10/23/2015
BLA 761036/0.0	DARZALEX	DARATUMUMAB	JANSSEN BIOTECH, INC.	P,O	11/16/2015
BLA 761035/0.0	EMPLICITI	ELOTUZUMAB	BRISTOL-MYERS SQUIBB COMPANY	P,O	11/30/2015
BLA 125561/0.0	KANUMA	SEBELIPASE ALFA	SYNAGEVA BIOPHARMA CORP	P,O	12/8/2015

(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).