CDER Drug and Biologic Restricted Distribution Approvals
As of June 30, 2018

NDA and BLA Restricted Distribution Approvals

Application Number	Proprietary Name	Established Name	Applicant	FDA Received Date	Approval Date	Total Time to Approval (Months)	Approval Basis	Approval Indication
NDA 022081	LETAIRIS	AMBRISENTAN	GILEAD SCIENCES	12/18/2006	6/15/2007	5.9	R	PULMONARY HYPERTENSION
NDA 021880	REVLIMID	LENALIDOMIDE	CELGENE CORP	4/7/2005	12/27/2005	8.7	R	TREATMENT OF PATIENTS WITH TRANSFUSION-DEPENDENT ANEMIA
NDA 021320	PLENAXIS	ABARELIX	SPECIALITY EUROPEAN PHARMA LTD	12/12/2000	11/25/2003	35.4	R	TREATMENT FOR PROSTATIC CANCER WHERE ORCHIECTOMY/ESTROGEN ADMINISTRATION/OR AGONIST THERAPY IN EITHER NOT INDICATED/ UNACCEPTABLE TO THE PATIENT
NDA 021196	XYREM	SODIUM OXYBATE	JAZZ PHARMACEUTICALS	10/2/2000	7/17/2002	21.5	R	TREATMENT TO REDUCE THE INCIDENCE OF CATAPLEXY AND TO IMPROVE THE SYMPTOM OF DAYTIME SLEEPINESS IN PATIENTS WITH NARCOLEPSY
NDA 021290	TRACLEER	BOSENTAN	ACTELION PHARMACEUTICALS LTD	11/17/2000	11/20/2001	12.1	R	PULMONARY ARTERIAL HYPERTENSION
NDA 020687	MIFEPREX	MIFEPRISTONE	DANCO LABORATORIES LLC	3/18/1996	9/28/2000	18.0†	R	INDUCTION OF ABORTION
NDA 020747	ACTIQ	FENTANYL CITRATE	CEPHALON INC	11/13/1996	11/4/1998	23.7	R	MANAGEMENT OF BREAKTHROUGH CANCER PAIN IN PATIENTS WITH MALIGNANCIES WHO ARE ALREADY RECEIVING AND WHO ARE TOLERANT TO OPIOID THERAPY FOR THEIR UNDERLYING PERSISTENT CANCER PAIN
NDA 020785	THALOMID	THALIDOMIDE	CELGENE CORP	12/20/1996	7/16/1998	18.8	R	ACUTE TREATMENT OF ERYTHEMA NODOSUM LEPROSUM AS WELL AS FOR THE MAINTENANCE THERAPY FOR PREVENTION AND SUPPRESSION ERYTHEMA NODOSUM LEPOSUM IN HANSEN'S DISEASE
Supplements								
NDA 021880 / 1	REVLIMID	LENALIDOMIDE	CELGENE CORP	12/30/2005	6/29/2006	6.0	R	IN COMBINATION WITH DEXAMETHASONE FOR THE TREATMENT OF MULTIPLE MYELOMA PATIENTS WHO HAVE RECEIVED AT LEAST ONE PRIOR THERAPY
BLA 125104 / 15	NATALIZUMAB	TYSABRI	BIOGEN INC	9/27/2005	6/5/2006	8.3	R	TREATMENT OF PATIENTS WITH RELAPSING FORMS OF MULTIPLE SCLEROSIS (MS) TO DELAY THE ACCUMULATION OF PHYSICAL DISABILITY AND REDUCE THE FREQUENCY OF CLINICAL EXACERBATIONS
NDA 018662 / 56	ACCUTANE	ISOTRETINOIN	HOFFMANN LA ROCHE INC	6/27/2005	8/12/2005	1.5	R	BECAUSE OF THE TERATOGENICITY OF ISOTRETINOIN, PROPOSES THE IPLEDGE PROGRAM, AN ENHANCED RISK MINIMIZATION ACTION PLAN (RISKMAP) DESIGNED TO MINIMIZE DRUG EXPOSURE DURING PREGNANCY

NDA 021107 / 5	LOTRONEX	ALOSETRON HYDROCHLORIDE	SEBELA IRELAND LTD	12/7/2001	6/7/2002	6.0	R	THIS SUPPLEMENTAL APPLICATION PROVIDES FOR THE USE OF LOTRONEX ONLY FOR WOMEN WITH SEVERE DIARRHEA-PREDOMINANT IRRITABLE BOWEL SYNDROME (IBS) WHO HAVE: • CHRONIC IBS SYMPTOMS (GENERALLY LASTING 6 MONTHS OR LONGER), • HAD ANATOMIC OR BIOCHEMICAL ABNORMALITIES OF THE GASTROINTESTINAL TRACT EXCLUDED, AND • FAILED TO RESPOND TO CONVENTIONAL THERAPY. DIARRHEA-PREDOMINANT IBS IS SEVERE IF IT INCLUDES DIARRHEA AND ONE OR MORE OF THE FOLLOWING: • FREQUENT AND SEVERE ABDOMINAL PAIN/DISCOMFORT • FREQUENT BOWEL URGENCY OR FECAL INCONTINENCE • DISABILITY OR RESTRICTION OF DAILY ACTIVITIES DUE TO IBS

The Therapeutic Biologic Products transferred from CBER to CDER effective 1-Oct-03.

R - Restricted - Approval with restrictions to assure safe use as recorded in 21 CFR 601.42 (Subpart E) or 21 CFR 314.520 (Subpart H).

†-- Total approval time was adjusted based on management decision. This is a legacy practice and is no longer exercised.