CDER Drug and Biologic Accelerated Approvals
As of September 30, 2011

Last Refresh Date: 10/17/2011

NDAs Approved Under Subpart H

NDA Number	Product Name	FDA Received Date	Approval Date	Total Approval Time (Months)	Approval Basis	Indication
NDA 202570	XALKORI	3/30/2011	8/26/2011	4.9	S	FOR THE TREATMENT OF PATIENTS WITH LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) THAT IS ANAPLASTIC LYMPHOMA KINASE (ALK)-POSITIVE AS DETECTED BY AN FDA APPROVED TEST
NDA 021945	MAKENA (HYDROXYPROGESTERONE CAPROATE)	4/20/2006	2/3/2011	57.5	S	TO REDUCE THE RISK OF PRETERM BIRTH IN WOMEN WITH A SINGLETON PREGNANCY WHO HAVE A HISTORY OF SINGLETON SPONTANEOUS PRETERM BIRTH.
NDA 022468	FOLOTYN	3/24/2009	9/24/2009	6.0	S	RELAPSED OR REFRACTORY PERIPERAL T-CELL LYMPHOMA
NDA 022273	FLUDARABINE PHOSPHATE TABS FOR ORAL USE	11/19/2007	12/18/2008	13.0	S	TREATMENT OF ADULTS PTS WITH B CELL CHRONIC LYMPHOCYTIC LEUEMIA (CLL) WHO HAVE NOT RESPONDED TO WHOSE DISEASE HAS PROGRESSED DURING OR AFTER TREATMENT WITH AT
NDA 022291	PROMACTA	12/19/2007	11/20/2008	11.1	S	SHORT TERM IDIOPATHIC THROMBOCYTOPAENIC PUPURA (ITP)
NDA 022187	TMC 125 ETRAVIRINE	7/18/2007	1/18/2008	6.0	S	TREATMENT OF HIV
NDA 022068	TASIGNA (NILOTINIB, AMN107)	9/29/2006	10/29/2007	13.0	S	TREATMENT OF GLEEVEC RESISTANT OR INTOLERANT ADULT PTS WITH PHILADELPHIA CHROMOSONE POSITIVE CHRONIC MYELOGENOUS LEUKEMIA IN CHRONIC PHASE & ACCELERATED PHASE
NDA 022145	ISENTRESS	4/13/2007	10/12/2007	6.0	S	IN COMBINATION WITH OTHER ANTIRETROVIRAL AGENTS FOR THE TREATMENT OF HIV 1 INFECTION
NDA 022128	SELZENTRY, MARAVIROC, UK-427,857	12/20/2006	8/6/2007	7.5	S	TREATMENT OF PATIENTS WITH CCR5-TROPIC HIV-1
NDA 022081	LETAIRIS	12/18/2006	6/15/2007	5.9	R	PULMONARY HYPERTENSION
NDA 021986	SPRYCEL	12/28/2005	6/28/2006	6.0	R	FOR CHRONIC MYELOGENOUS LEUKEMIA
NDA 021976	PREZISTA	12/23/2005	6/23/2006	6.0	S	TREATMENT OF HIV INFECTION
NDA 021880	REVLIMID(LENALIDOMIDE)	4/7/2005	12/27/2005	8.7	S	TREATMENT OF PATIENTS WITH TRANSFUSION-DEPENDENT ANEMIA
NDA 021882	EXJADE (DEFERASIRIX)	5/2/2005	11/2/2005	6.0	S	TREATMENT OF CHRONIC IRON OVERLOAD DUE TO BLOOD TRANSFUSIONS IN ADULT AND PEDIATRIC PATIENTS AS YOUNG AS TWO YEARS OF AGE.
NDA 021877	ARRANON (NELARABINE)	4/29/2005	10/28/2005	6.0	S	TREATMENT OF PEDIATRIC AND ADULT PATIENTS WITH T-CELL ACUTE LYMPHOBLASTIC LEUKEMIA OR T-CELL LYMPHOBLASTIC LYMPHOMA

NDA 021814	APTIVUS (TIPRANAVIR) 250MG CAPSULES	12/22/2004	6/22/2005	6.0	S	TREATMENT OF HIV-1 INFECTION
NDA 021673	CLOFARABINE	3/30/2004	12/28/2004	9.0	S	TREATMENT OF ACUTE LYMPHOCYTIC LEUKEMIA
NDA 021322	LUVERIS (LUTROPIN ALPHA) INJ 75IU	5/1/2001	10/8/2004	41.3	S	LUVERIS ADMINISTERED WITH FOLLITROPIN ALFA FOR INJECTION IS INDICATED FOR STIMULATION OF FOLLICULAR DEVELOPMENT IN WOMEN WITH SEVERE DEFICIENCY IN LH AND FSH
NDA 021752	EMTRICITABINE 200MG/TENOFOVIR DISOPROXIL	3/12/2004	8/2/2004	4.7	S	TREATMENT OF HIV INFECTION
NDA 021320	PLENAXIS DEPOT (ABARELIX) DEPOT SUSPENSI	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 021602	VELCADE (BORTEZOMIB) INJ 3.5MG	1/21/2003	5/13/2003	3.7	S	TREATMENT OF RELAPSED/REFRACTORY MULTIPLE MYELOMA
NDA 021399	IRESSA (GEFITINIB) TABLETS	8/5/2002	5/5/2003	9.0	S	TREATMENT OF NON-SMALL CELL LUNG CANCER
NDA 021588	GLEEVEC (IMATINIB MESYLATE) 100/400MG	12/16/2002	4/18/2003	4.0	S	TREATMENT OF PHILADELPHIA POSITIVE CHRONIC MYELOID LEUKEMIA
NDA 021481	FUZEON	9/16/2002	3/13/2003	5.9	S	TREATMENT OF HIV1/AIDS
NDA 021492	ELOXATIN(OXALIPLATIN)INJECTION 50MG/100M	6/24/2002	8/9/2002	1.5	S	TREATMENT FOR COLORECTAL CANCER
NDA 021196	XYREM (SODIUM OXYBATE) 500MG/ML ORAL SOL	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 021272	REMODULIN(TREPROSTINIL SODIUM)1/2.5/10	10/16/2000	5/21/2002	19.1	S	TREATMENT FOR PULMONARY ARTERIAL HYPERTENSION
NDA 021290	TRACLEER	11/17/2000	11/20/2001	12.1	R	PULMONARY ARTERIAL HYPERTENSION
NDA 021356	VIREAD(TENOFOVIR DISOPROXIL FUMARATE)300	5/1/2001	10/26/2001	5.9	S	TREATMENT OF HIV-1 INFECTION IN ADULTS
NDA 021335	GLEEVEC (IMATINIB MESYLATE) 50/100 MG	2/27/2001	5/10/2001	2.4	S	TREATMENT OF CHRONIC MYELOID LEUKEMIA
NDA 021205	TRIZIVIR	12/17/1999	11/14/2000	10.9	S	TREATMENT OF HIV INFECTION
NDA 020687	MIFEPREX	3/18/1996	9/28/2000	18.0e	R	INDUCTION OF ABORTION
NDA 021226	KALETRA	6/1/2000	9/15/2000	3.5	S	TREATMENT OF HIV INFECTION
NDA 021251	KALETRA	6/1/2000	9/15/2000	3.5	S	TREATMENT OF HIV
NDA 021174	MYLOTARG	10/29/1999	5/17/2000	6.6	S	TREATMENT OF RELAPSED ACUTE MYELOID LEUKEMIA
NDA 050747	SYNERCID(DALFOPRISTIN/QUINUPRISTIN)IV 50	9/5/1997	9/21/1999	7.8d	S	INFECTIONS DUE TO VREF INCLUDING CASES ASSOCIATED WITH CONCURRENT BACTEREMIA AND INFECTIONS CAUSED BY STAPHYLOCOCCUS AUREAS/INCLUDING METHICILLIN SUSCEPTIBLE AN
NDA 021029	TEMODAR (TEMOZOLOMIDE)	8/13/1998	8/11/1999	11.9	S	TREATMENT OF RECURRENT GLIOMA/ADVANCED METASTATIC MELANOMA
NDA 021007*	AGENERASE	10/16/1998	4/15/1999	6.0	S	TREATMENT OF HIV-1 INFECTION
NDA 021039*	AGENERASE	12/8/1998	4/15/1999	4.2	S	TREATMENT OF HIV INFECTION
NDA 021041	DEPOCYT	10/5/1998	4/1/1999	5.9	S	INTRATHECAL TREATMENT OF LYMPHOMATOUS MENINGITIS

NDA 020977	ZIAGEN	6/24/1998	12/17/1998	5.8	S	TREATMENT OF HIV INFECTION
NDA 020978	ZIAGEN	6/24/1998	12/17/1998	5.8	S	TREATMENT OF HIV INFECTIONS
NDA 020747	ACTIQ (ORAL TRANSMUCOSAL FENTANYL CITRAT	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 020972	SUSTIVA	6/11/1998	9/17/1998	3.2	S	TREATMENT OF HIV
NDA 020933	VIRAMUNE (NEVIRAPINE) SUSPENSION	4/20/1998	9/11/1998	4.7	S	FOR USE IN COMBINATION WITH OTHER ANTIRETROVIRAL AGENTS FOR TREATMENT OF HIV-1 INFECTION
NDA 020785	THALOMID (THALIDOMIDE) 50MG CAPSULES	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
NDA 021024	PRIFTIN (RIFAPENTINE) 150 MGS TABLETS	12/22/1997	6/22/1998	6.0	S	TREATMENT OF PULMONARY TUBERCULOSIS
NDA 019832	SULFAMYLON	3/31/1997	6/5/1998	14.2c	S	ADJUNCTIVE THERAPY IN PATIENTS WITH SECOND AND THIRD-DEGREE BURNS.
NDA 020896	XELODA	10/31/1997	4/30/1998	6.0	S	TREATMENT OF METASTATIC BREAST CANCER
NDA 020705	RESCRIPTOR	7/15/1996	4/4/1997	8.6	S	TREATMENT OF HIV-1 INFECTION
NDA 020778	VIRACEPT (NELFINAVIR MESYLATE) PEDIATRIC	12/26/1996	3/14/1997	2.6	S	TREATMENT OF HIV INFECTION IN CHILDREN WHEN ANTIRETROVIRAL THERAPY IS INDICATED
NDA 020779	VIRACEPT (NELFINAVIR MESYLATE) 250MG TAB	12/26/1996	3/14/1997	2.6	S	TREATMENT OF HIV INFECTION WHEN ANTIRETROVIRAL THERAPY IS WARRANTED
NDA 019815	PROAMATINE	9/25/1995	9/6/1996	11.4b	S	IDIOPATHIC ORTHOSTATIC HYPROTENSION
NDA 020604	SEROSTIM (SOMATROPIN) FOR INJECTION 6MG	9/11/1995	8/23/1996	11.4	S	TREATMENT OF AIDS WASTING AND CACHEXIA
NDA 020636	VIRAMUNE (NEVIRAPINE) ORAL TABS 200MG	2/23/1996	6/21/1996	3.9	S	COMBINATION OF VIRAMUNE WITH NUCLEOSIDE ANTIRETROVIRAL AGENTS IN PREVIOUSLY TREATED PATIENTS FOR WHOM CURRENT THERAPY IS DEEMED INADEQUATE
NDA 020571	CAMPTOSAR (IRINOTECAN HCL TRIHYDROTE) IV	12/28/1995	6/14/1996	5.6	S	FOR REFRACTORY COLO RECTAL CANCER
NDA 020449	TAXOTERE	7/27/1994	5/14/1996	21.6	S	PATIENTS WITH LOCALLY ADVANCED OR METASTATIC BREAST CARCINOMA IN WHOM PREVIOUSTHERAPY HAS FAILED / PATIENTS WITH LOCALLY ADVANCED OR METASTATIC NON SMALL CEL
NDA 020685	CRIXIVAN	1/31/1996	3/13/1996	1.4	S	TREATMENT OF ADULTS WITH HIV-1 INFECTIONS
NDA 020680	NORVIR (RITONAVIR)	12/21/1995	3/1/1996	2.3	S	TREATMENT OF HIV INFECTION
NDA 020659	NORVIR (RITONAVIR) ORAL SOLUTION	12/21/1995	3/1/1996	2.3	S	TO TREAT HIV INFECTION

NDA 020628	INVIRASE(SAQUINAVIR MESYLATE) 200MG CAPS	8/31/1995	12/6/1995	3.2	S	MONOTHERAPY AND COMBINATION TREATMENT (WITH HIVID AND/OR ZDV) FOR PATIENTS WITHADVANCED HIV INFECTION
NDA 020596	EPIVIR	7/7/1995	11/17/1995	4.4	S	TREATMENT OF HIV INFECTION IN SELECTED PATIENTS
NDA 050718	DOXIL	9/7/1994	11/17/1995	14.3	S	TREATMENT OF KAPOSI'S SARCOMA IN AIDS PATIENTS WHO HAVE FAILED PRIOR SYSTEMIC COMBINATION CHEMOTHERAPY EITHER DUE TO PROGRESSION OF DISEASE OR UNACCEPTABLE TOXI
NDA 020564	EPIVIR	7/7/1995	11/17/1995	4.4	S	TREATMENT OF HIV INFECTION IN SELECTED PATIENTS
NDA 020498	CASODEX	9/14/1994	10/4/1995	12.7	S	USE IN COMBINATION THERAPY WITH EITHER AN LHRH ANALOGUE OR SURGICAL CASTRATION FOR THE TREATMENT OF ADVANCED PROSTATE CANCER
NDA 020212	ZINECARD	8/5/1994	5/26/1995	9.7a	S	ZINECARD FOR INJECTION IS INDICATED FOR THE PREVENTION OF CARDIOMYOPATHY ASSOCIATED WITH DOXORUBICIN ADMINISTRATION
NDA 020412	ZERIT (STAVUDINE) CAPS 5/15/20/30/40MG	11/2/1992	12/23/1993	13.7	S	ADULT PATIENTS WITH HIV INFECTION WHO HAVE RECEIVED ZIDOVUDINE THERAPY AND PEDIATRIC PATIENTS 3 MO TO 12 YRS WITH SYMPTOMATIC HIV INFECTION OR WITH SIGNIFICANT
NDA 050698	BIAXIN	11/2/1992	12/23/1993	13.7	S	ANTIBIOTIC PEDIATRIC SUSPENSION
NDA 020199*	HIVID (ZALCITABINE) TABLETS	10/31/1991	6/19/1992	7.6	S	TREATMENT OF HIV-INFECTED PATIENTS WITH AIDS OR ADVANCED AIDS-RELATED COMPLEX

NDA Efficacy Supplements Approved Under Subpart H

NDA Supplement Number	Supplement Type	Product Name	FDA Received Date	Approval Date	Total Approval Time (Months)	Approval Basis
NDA 022334 / 6	NEW INDICATION	AFINITOR	4/30/2010	10/29/2010	6.0	S
NDA 021986 / 8	NEW INDICATION	SPRYCEL	4/28/2010	10/28/2010	6.0	S
NDA 022068 / 5	NEW INDICATION	TASIGNA (NILOTINIB, AMN107)	12/21/2009	6/17/2010	5.9	S
NDA 022059 / 7	NEW INDICATION	TYKERB TABLETS	3/31/2009	1/29/2010	10.0	S
NDA 022187 / 1	ACCELERATED APPROVAL CONFIRMATORY STUDY	TMC 125 ETRAVIRINE	1/30/2009	11/24/2009	9.8	S
NDA 021588 / 25	NEW INDICATION	GLEEVEC (IMATINIB MESYLATE) 100/400MG	6/24/2008	12/19/2008	5.9	S
NDA 021462 / 15	NEW INDICATION	ALIMTA (PEMETREXED DISODIUM) 500MG VIALS	8/28/2007	9/26/2008	13.0	S
NDA 050718 / 33	ACCELERATED APPROVAL CONFIRMATORY STUDY	DOXIL	8/10/2007	6/10/2008	10.0	S
NDA 020634 / 47	NEW PATIENT POPULATION	LEVAQUIN	7/5/2007	5/5/2008	10.0	S
NDA 020635 / 51	NEW PATIENT POPULATION	LEVAQUIN	7/5/2007	5/5/2008	10.0	S
NDA 021721 / 15	NEW PATIENT POPULATION	LEVAQUIN(LEVOFLAXIN ORAL SOLUTION)25MG/M	7/5/2007	5/5/2008	10.0	S
NDA 021588 / 16	NEW INDICATION	GLEEVEC (IMATINIB MESYLATE) 100/400MG	3/28/2006	9/27/2006	6.0	S
NDA 021880 / 1	NEW INDICATION	REVLIMID(LENALIDOMIDE)	12/30/2005	6/29/2006	6.0	R

NDA 021430 / 1	TYPE 6 NDA	THALOMID (THALIDOMIDE) 50MG/100MG/200MG	12/23/2003	5/25/2006	29.1	R,S
NDA 021968 / 1	TYPE 6 NDA	SUTENT (SUNITINIB)	8/11/2005	1/26/2006	5.5	S
NDA 020726 / 12	NEW INDICATION	FEMARA	6/28/2005	12/28/2005	6.0	S
NDA 020634 / 35	NEW INDICATION	LEVAQUIN	5/26/2004	11/24/2004	6.0	S
NDA 020635 / 35	NEW INDICATION	LEVAQUIN	5/26/2004	11/24/2004	6.0	S
NDA 021272 / 2	NEW ROUTE OF ADMINISTRATION	REMODULIN(TREPROSTINIL SODIUM)1/2.5/10	1/30/2004	11/24/2004	9.8	S
NDA 021721 / 3	NEW INDICATION	LEVAQUIN(LEVOFLAXIN ORAL SOLUTION)25MG/M	11/12/2004	11/24/2004	0.4	S
NDA 020726 / 11	NEW INDICATION	FEMARA	4/29/2004	10/29/2004	6.0	S
NDA 021677 / 1	TYPE 6 NDA	ALIMTA (PEMETREXED DISODIUM) 500MG VIALS	11/4/2003	8/19/2004	9.5	S
NDA 019858 / 21*	NEW INDICATION	CIPRO IN SODIUM CHLORIDE 0.9% IN PLASTIC	3/2/2000	8/30/2000	6.0	S
NDA 021335 / 3	NEW PATIENT POPULATION	GLEEVEC (IMATINIB MESYLATE) 50/100 MG	6/28/2002	5/20/2003	10.7	S
NDA 021588 / 1	NEW PATIENT POPULATION	GLEEVEC (IMATINIB MESYLATE) 100/400MG	4/24/2003	5/20/2003	0.9	S
NDA 021335 / 4	NEW INDICATION	GLEEVEC (IMATINIB MESYLATE) 50/100 MG	6/28/2002	12/20/2002	5.8	S
NDA 020541 / 10	NEW INDICATION	ARIMIDEX	3/5/2002	9/5/2002	6.0	S
NDA 021107 / 5	LABELING CHANGE WITH CLINICAL DATA	LOTRONEX	12/7/2001	6/7/2002	6.0	R
NDA 021335 / 1	NEW INDICATION	GLEEVEC (IMATINIB MESYLATE) 50/100 MG	10/16/2001	2/1/2002	3.6	S
NDA 019537 / 38	NEW INDICATION	CIPRO	3/1/2000	8/30/2000	6.0	S
NDA 019847 / 24	NEW INDICATION	CIPRO	3/2/2000	8/30/2000	6.0	S
NDA 019857 / 27	NEW INDICATION	CIPRO IN DEXTROSE 5% IN PLASTIC CONTAINE	3/2/2000	8/30/2000	6.0	S
NDA 020780 / 8	NEW INDICATION	CIPRO	3/2/2000	8/30/2000	6.0	S
NDA 021156 / 1	TYPE 6 NDA	CELEBREX (CELECOXIB) 200MG CAPSULES	6/25/1999	12/23/1999	6.0	S
NDA 050718 / 6	NEW INDICATION	DOXIL	12/29/1998	6/28/1999	6.0	S
NDA 020636 / 9	NEW INDICATION	VIRAMUNE (NEVIRAPINE) ORAL TABS 200MG	3/16/1998	9/11/1998	5.9	S
NDA 020221 / 2	NEW INDICATION	ETHYOL	2/9/1996	3/15/1996	1.2	S
NDA 050697 / 1	TYPE 6 NDA	BIAXIN	11/2/1992	12/23/1993	13.7	S
NDA 022393 / 4	NEW INDICATION	ROMIDEPSIN FOR INFUSION	12/17/2010	6/16/2011	6.0	S

NDA Labeling Supplements Approved Under Subpart H

NDA Supplement Number	Supplement Type	Product Name	FDA Received Date	Approval Date	Total Approval Time (Months)	Approval Basis
NDA 020785 / 31	LABELING SUPPLEMENT	THALOMID (THALIDOMIDE) 50MG CAPSULES	5/24/2005	5/25/2006	12.0	R,S
NDA 018662 / 56*	LABELING SUPPLEMENT	ACCUTANE	6/27/2005	8/12/2005	1.5	R
NDA 021462 / 1	LABELING SUPPLEMENT	ALIMTA (PEMETREXED DISODIUM) 500MG VIALS	8/13/2004	8/19/2004	0.2	S

BLAs Approved Under Subpart E

BLA Number	Product Name	FDA Received Date	Approval Date	Total Approval Time (Months)	Approval Basis	Indication
L 125388/0.0	BRENTUXIMAB VEDOTIN	2/28/2011	8/19/2011	5.7	S	THE TREATMENT OF PATIENTS WITH HODGKIN LYMPHOMA AFTER FAILURE OF AUTOLOGOUS STEM CELL TRANSPLANT (ASCT) OR AFTER FAILURE OF AT LEAST TWO PRIOR MULTI-AGENT CHEMOTHERAPY REGIMENS IN PATIENTS WHO ARE NOT ASCT CANDIDATES
L 125399/0.0	BRENTUXIMAB VEDOTIN	2/28/2011	8/19/2011	5.7	S	THE TREATMENT OF PATIENTS WITH SYSTEMIC ANAPLASTIC LARGE CELL LYMPHOMA (SALCL) AFTER FAILURE OF AT LEAST ONE PRIOR MULTI-AGENT CHEMOTHERAPY REGIMEN.
L 125326/0.0	OFATUMUMAB	1/30/2009	10/26/2009	8.8	S	TREATMENT OF PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA (CLL) REFRACTORY TO FLUDARABINE AND ALEMTUZUMAB
L 125147/0.0	PANITUMUMAB	3/29/2006	9/27/2006	6.0	S	BLA - TREATMENT OF EGFR-EXPRESSING, METASTATIC COLORECTAL CARCINOMA WITH DISEASE PROGRESSION ON OR FOLLOWING FLUOROPYRIMIDINE-, OXALIPLATIN-, AND IRINOTECAN-CONTAINING CHEMOTHERAPY REGIMENS
L 125104/0.0	NATALIZUMAB	5/24/2004	11/23/2004	6.0	S	BLA - TREATMENT OF PATIENTS WITH RELAPSING FORMS OF MULTIPLE SCLEROSIS (MS) TO REDUCE THE FREQUENCY OF CLINICAL EXACERBATIONS
L 125084/0.0	CETUXIMAB	8/14/2003	2/12/2004	6.0	S	BLA - TREATMENT OF EGFR-EXPRESSING, METASTATIC COLORECTAL CARCINOMA IN PATIENTS WHO ARE REFRACTORY TO IRINOTECAN BASED CHEMOTHERAPY (IN COMBINATION WITH IRINOTECAN); TREATMENT OF EGFR-EXPRESSING, METASTATIC COLORECTAL CARCINOMA IN PATIENTS WHO ARE INTOLER
L 103979/0.0	AGALSIDASE BETA	6/23/2000	4/24/2003	34.0	S	BLA - USE IN PATIENTS WITH FABRY DISEASE TO REDUCE GLOBOTRIAOSYLCERAMIDE (GL-3) DEPOSITION IN CAPILLARY ENDOTHELIUM OF THE KIDNEY AND CERTAIN OTHER CELL TYPES

L 125019/0.0	IBRITUMOMAB TIUXETAN	11/1/2000	2/19/2002	15.6	S	BLA - (ACC. APP.) TREATMENT OF PATIENTS WITH RELAPSED OR REFRACTORY LOW-GRADE, FOLLICULAR, OR TRANSFORMED B-CELL NON-HODGKIN'S LYMPHOMA: (NOT ACC. APP.) INCLUDING PATIENTS WITH RITUXIMAB (RITUXAN) REFRACTORY FOLLICULAR NON-HODGKIN'S LYMPHOMA
L 103948/0.0	ALEMTUZUMAB	12/23/1999	5/7/2001	16.5	S	BLA - TREATMENT OF B-CELL CHRONIC LYMPHOCYTIC LEUKEMIA (B-CLL) IN PATIENTS WHO HAVE BEEN TREATED WITH ALKYLATING AGENTS AND WHO HAVE FAILED FLUDARABINE THERAPY
L 103767/0.0	DENILEUKIN DIFTITOX	12/9/1997	2/5/1999	13.9	S	BLA - TREATMENT OF PERSISTENT OR RECURRENT CUTANEOUS T-CELL LYMPHOMA (ORPHAN INDICATION)
L 103772/0.0	INFLIXIMAB	12/30/1997	8/24/1998	7.8	S	BLA - TREATMENT OF MODERATELY TO SEVERELY ACTIVE CROHN'S DISEASE FOR THE REDUCTION OF THE SIGNS AND SYMPTOMS, IN PATIENTS WHO HAVE AN INADEQUATE RESPONSE TO CONVENTIONAL THERAPIES AND TREATMENT OF PATIENTS WITH FISTULIZING CROHN'S DISEASE FOR THE REDUCTIO
L 103471/0.0	INTERFERON BETA-1B	6/18/1992	7/23/1993	13.2	S	PLA - TREATMENT OF MULTIPLE SCLEROSIS (ORPHAN DESIGNATION)

BLA Efficacy Supplements Approved Under Subpart E

BLA Supplement Number	Product Name	FDA Received Date	Approval Date	Total Approval Time (Months)	Approval Basis	Indication
L 125104/15.0	NATALIZUMAB	27-Sep-05	5-Jun-06	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; ADD A BOXED WARNING AND UPDATE THE CLINICAL PHARMACOLOGY, CLINICAL STUDIES, INDICATION AND USAGE, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, AND ADVERSE REACTIONS SECTIONS OF THE PACKAGE INSERT WITH SAFETY AND EFFICACY DATA (RISK MANAGEMENT PLAN)

L 125011/24.0	TOSITUMOMAB AND IODINE I 131 TOSITUMOMAB	3-Jul-04	22-Dec-04	5.7	S	EXPAND THE INDICATION TO INCLUDE PATIENTS WITH RELAPSED OR REFRACTORY, LOW GRADE, FOLLICULAR OR TRANSFORMED CD20 POSITIVE NON-HODGKIN'S LYMPHOMA WHO HAVE NOT RECEIVED RITUXIMAB

BLA Labeling Supplements Approved Under Subpart E

BLA Supplement Number	Product Name	FDA Received Date	Approval Date	Total Approval Time (Months)	Approval Basis	Indication
There are no accelerated approvals at this time						

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).
S - Surrogate - Approval based on a surrogate endpoint or on an effect on a clinical endpoint other than survival or irreversible morbidity as recorded in 21 CFR 601.41 (Subpart E) .
or 21 CFR 314.510 (Subpart H)

*- Submission is currently Withdrawn After Approval and listed in the Federal Register.
a -- Approval time based on the receipt of significant new clinical data on 8/4/94 supporting a new indication. The original receipt date of this application was 2/10/92.
b -- Significant new clinical data needed for approval was received on 9/25/95; before this only partial clinical data had been received. This date was used to calculate total approval time.
The original receipt date was (28-Apr-88).
c -- Significant new clinical data supporting a new indication were received on 31-Mar-97. This date was used to calculate the total approval time. The original receipt date was 19-Feb-88.
d -- The total approval time was adjusted for N 50747 because of a negative plant inspection. The time period until an acceptable inspection was received (05-Mar-98 to 26-Jul-99)
was excluded from this time.
e -- The total approval time for N 20687, Mifeprex was adjusted. The time period from 9-18-96 to 8-19-99 was excluded because the sponsor had to find a new manufacturer,
the final study report for the US clinical trial was completed and submitted late in the review, and stability issues had to be addressed before the sponsor could resubmit the application for review
The time period from 2-18-00 to 3-31-00 was excluded while the sponsor prepared for another facilities inspection.