

**New Drug Application (NDA) & Biologic License Application (BLA) Efficacy Supplement Calendar Year Approvals
As of December 31, 2012**

Selection Criteria:

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APPLICATION NUMBER	SUBMISSION TYPE & NUMBER	SUPPLEMENT TYPE or SUBMISSION CLASS CODE	ESTABLISHED NAME	APPLICANT	PRIORITY REVIEW	RECEIPT DATE	APPROVAL DATE	TOTAL APPROVAL TIME (MONTHS)	INDICATION/DESCRIPTION
NDA 019599	SUPPL-11	NEW DOSING REGIMEN	NAFTIFINE HYDROCHLORIDE	MERZ PHARMACEUTICALS LLC	S	12/16/2010	1/13/2012	12.9	PROVIDES FOR A CHANGE IN STRENGTH AND DOSAGE
NDA 050779	SUPPL-18	NEW DOSING REGIMEN	CEFAZOLIN SODIUM/ DEXTROSE	B BRAUN MEDICAL INC	S	12/10/2008	1/13/2012	37.1	PROVIDES FOR AN ADDITIONAL STRENGTH OF 2G FOR THE DRUG PRODUCT CEFAZOLIN FOR INJECTION USP AND DEXTROSE INJECTION USP IN THE DUPLEX CONTAINER
NDA 021356	SUPPL-38	MANUFACTURING CHANGE WITH CLINICAL DATA	TENOFOVIR DISOPROXIL FUMARATE	GILEAD SCIENCES INC	P	6/16/2011	1/18/2012	7.1	PROVIDES FOR THE USE OF 150MG, 200MG, AND 250MG TABLETS IN COMBINATION WITH OTHER ANTIRETROVIRAL AGENTS FOR THE TREATMENT OF HIV-1 INFECTION IN PEDIATRIC PATIENTS 2 TO LESS THAN 12 YEARS OF AGE, WEIGHING GREATER THAN OR EQUAL TO 17 KG, WHO CAN SWALLOW AN INTACT TABLET
NDA 021602	SUPPL-27	NEW ROUTE OF ADMINISTRATION	BORTEZOMIB	MILLENNIUM PHARMACEUTICALS INC	S	3/23/2011	1/23/2012	10.1	PROVIDES FOR A SUBCUTANEOUS ROUTE OF ADMINISTRATION AS AN ALTERNATIVE TO THE EXISTING INTRAVENOUS ROUTE OF ADMINISTRATION
NDA 021588	SUPPL-35	ACCELERATED APPROVAL CONFIRMATORY STUDY	IMATINIB MESYLATE	NOVARTIS PHARMACEUTICALS CORP	P	8/2/2011	1/31/2012	6.0	PROVIDES FOR THE CONVERSION OF ACCELERATED APPROVAL TO FULL APPROVAL OF THE INDICATION FOR ADJUVANT TREATMENT OF ADULT PATIENTS FOLLOWING COMPLETE RESECTION OF KIT (CD117) POSITIVE GASTROINTESTINAL STROMAL TUMORS (GIST) AND PROVIDES UPDATED GLEEVEC PRESCRIBING INFORMATION
NDA 021977	SUPPL-22	NEW PATIENT POPULATION	LISDEXAMFETAMINE DIMESYLATE	SHIRE DEVELOPMENT INC	S	3/31/2011	1/31/2012	10.1	PROVIDES FOR THE MAINTENANCE TREATMENT OF ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD) IN ADULTS
NDA 021355	SUPPL-3	NEW DOSING REGIMEN	DROSPIRENONE/ 17B- ESTRADIOL	BAYER HEALTHCARE PHARMACEUTICALS INC	S	4/29/2011	2/29/2012	10.1	PROVIDES FOR THE INDICATION IN WOMEN WITH AN INTACT UTERUS FOR THE TREATMENT OF VASOMOTOR SYMPTOMS DUE TO MENOPAUSE
NDA 200678	SUPPL-3	NEW INDICATION	SAXAGLIPTIN/ METFORMIN HYDROCHLORIDE	BRISTOL MYERS SQUIBB	S	5/18/2011	3/7/2012	9.7	PROVIDES FOR MODIFICATIONS TO THE MEDICATION GUIDE, CHANGES TO THE RECENT MAJOR CHANGES, INDICATIONS AND USAGE, WARNINGS AND PRECAUTIONS AND ADVERSE REACTIONS SECTIONS OF THE HIGHLIGHTS OF PRESCRIBING INFORMATION SECTION, AND CHANGES TO THE INDICATIONS AND USAGE, DOSAGE AND ADMINISTRATION, WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS, CLINICAL PHARMACOLOGY AND CLINICAL STUDIES SECTIONS OF THE FULL PRESCRIBING INFORMATION SECTION OF THE KOMBIGLYZE XR PACKAGE INSERT
NDA 022252	ORIG-2	EFFICACY	ESTRADIOL VALERATE/ DIENOGEST	BAYER HEALTHCARE PHARMACEUTICALS INC	S	7/6/2009	3/14/2012	32.3	PROVIDES FOR THE TREATMENT OF HEAVY MENSTRUAL BLEEDING IN WOMEN WITHOUT ORGANIC PATHOLOGY WHO CHOOSE TO USE AN ORAL CONTRACEPTIVE AS THEIR METHOD OF CONTRACEPTION

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NDA 020829	SUPPL-59	NEW INDICATION	MONTELUKAST SODIUM	MERCK RESEARCH LABORATORIES DIV MERCK CO INC	S	5/26/2011	3/26/2012	10.0	EXPANDS THE CURRENT INDICATION FOR PREVENTION OF EXERCISE-INDUCED BRONCHOCONSTRICTION (EIB) IN PATIENTS 15 YEARS OF AGE AND OLDER TO INCLUDE PATIENTS 6 TO 14 YEARS OF AGE
NDA 020830	SUPPL-61	NEW INDICATION	MONTELUKAST SODIUM	MERCK AND CO INC	S	5/26/2011	3/26/2012	10.0	EXPANDS THE CURRENT INDICATION FOR PREVENTION OF EXERCISE-INDUCED BRONCHOCONSTRICTION (EIB) IN PATIENTS 15 YEARS OF AGE AND OLDER TO INCLUDE PATIENTS 6 TO 14 YEARS OF AGE
NDA 021409	SUPPL-36	NEW INDICATION	MONTELUKAST SODIUM	MERCK RESEARCH LABORATORIES DIV MERCK CO INC	S	5/26/2011	3/26/2012	10.0	EXPANDS THE CURRENT INDICATION FOR PREVENTION OF EXERCISE-INDUCED BRONCHOCONSTRICTION (EIB) IN PATIENTS 15 YEARS OF AGE AND OLDER TO INCLUDE PATIENTS 6 TO 14 YEARS OF AGE
NDA 022187	SUPPL-9	PEDIATRIC	ETRAVIRINE	JANSSEN RESEARCH AND DEVELOPMENT LLC	P	9/29/2011	3/26/2012	5.9	PROVIDES FOR A SCORED 25 MG TABLET AND EXPANDS THE INDICATION TO INCLUDE THE TREATMENT OF HIV-1 INFECTION, IN TREATMENT-EXPERIENCED PEDIATRIC PATIENTS 6 YEARS TO LESS THAN 18 YEARS OF AGE IN COMBINATION WITH OTHER ANTIRETROVIRAL AGENTS
NDA 202088	ORIG-2	EFFICACY	PHENTERMINE HYDROCHLORIDE	CITIUS PHARMACEUTICALS LLC	S	8/13/2010	3/27/2012	19.5	PROVIDES FOR THE SHORT-TERM (A FEW WEEKS) ADJUNCT IN A REGIMEN OF WEIGHT REDUCTION BASED ON EXERCISE, BEHAVIORAL MODIFICATION, AND CALORIC RESTRICTION IN THE MANAGEMENT OF EXOGENOUS OBESITY FOR PATIENTS WITH AN INITIAL BODY MASS INDEX \geq 30 KG/M ² , OR \geq 27 KG/M ² IN THE PRESENCE OF OTHER RISK FACTORS (E.G., CONTROLLED HYPERTENSION, DIABETES, HYPERLIPIDEMIA)
NDA 021829	SUPPL-1	NEW INDICATION	ROTIGOTINE	UCB INC	S	10/11/2007	4/2/2012	53.8	TO TREAT THE SIGNS AND SYMPTOMS OF MODERATE TO SEVERE PRIMARY RESTLESS LEGS SYNDROME (RLS)
NDA 021829	SUPPL-2	NEW INDICATION	ROTIGOTINE	UCB INC	S	10/11/2007	4/2/2012	53.8	TO TREAT THE SIGNS AND SYMPTOMS OF ADVANCED PARKINSON'S DISEASE (APD)
NDA 022341	SUPPL-9	NEW INDICATION	LIRAGLUTIDE	NOVO NORDISK INC	S	6/30/2011	4/6/2012	9.2	PROVIDES FOR THE REVISIONS TO THE PHYSICIAN INSERT (PI) BASED ON THE EFFICACY AND SAFETY RESULTS FROM STUDY NN2211-1842, ENTITLED THE EFFECT OF INSULIN DETEMIR IN COMBINATION WITH LIRAGLUTIDE AND METFORMIN COMPARED TO LIRAGLUTIDE AND METFORMIN IN SUBJECTS WITH TYPE 2 DIABETES. A 26-WEEK, RANDOMIZED, OPEN-LABEL, PARALLEL-GROUP, MULTICENTRE, MULTINATIONAL TRIAL WITH A 26-WEEK EXTENSION
NDA 022334	SUPPL-17	NEW INDICATION	EVEROLIMUS/ SUNITINIB	NOVARTIS PHARMACEUTICALS CORP	P	12/19/2011	4/26/2012	4.2	PROVIDES FOR THE TREATMENT OF ADULTS WITH RENAL ANGIOMYOLIPOMA AND TUBEROUS SCLEROSIS COMPLEX (TSC), NOT REQUIRING IMMEDIATE SURGERY

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NDA 022465	SUPPL-10	NEW INDICATION	PAZOPANIB	GLAXOSMITHKLINE	S	6/28/2011	4/26/2012	10.0	PROVIDES FOR THE TREATMENT OF PATIENTS WITH ADVANCED SOFT TISSUE SARCOMA (STS) WHO HAVE RECEIVED PRIOR CHEMOTHERAPY (LIMITATION OF USE: THE EFFICACY OF VOTRIENT FOR THE TREATMENT OF PATIENTS WITH ADIPOCYTIC STS OR GASTROINTESTINAL STROMAL TUMORS HAS NOT BEEN DEMONSTRATED)
NDA 200603	SUPPL-5	NEW DOSING REGIMEN	LURASIDONE HYDROCHLORIDE	SUNOVION PHARMACEUTICALS INC	S	6/28/2011	4/26/2012	10.0	PROVIDES FOR THE ADDITION OF THE 120 MG STRENGTH TABLET AND INCREASING MAXIMUM DOSING OF PATIENTS WITH SCHIZOPHRENIA TO 160 MG/DAY
NDA 020634	SUPPL-61	NEW INDICATION	LEVOFLOXACIN	JANSSEN PHARMACEUTICALS INC	P	10/28/2011	4/27/2012	6.0	PROVIDES FOR THE TREATMENT AND PROPHYLAXIS OF PLAGUE DUE TO YERSINIA PESTIS IN ADULTS AND PEDIATRIC PATIENTS 6 MONTHS OF AGE AND OLDER
NDA 020635	SUPPL-67	NEW INDICATION	LEVOFLOXACIN	JANSSEN PHARMACEUTICALS INC	P	11/7/2011	4/27/2012	5.7	PROVIDES FOR THE TREATMENT AND PROPHYLAXIS OF PLAGUE DUE TO YERSINIA PESTIS IN ADULTS AND PEDIATRIC PATIENTS 6 MONTHS OF AGE AND OLDER
NDA 021548	SUPPL-28	PEDIATRIC	FOSAMPRENAVIR CALCIUM	VIIV HEALTHCARE CO	P	10/28/2011	4/27/2012	6.0	PROVIDES FOR A NEW DOSING REGIMEN FOR LEXIVA, WITH RITONAVIR, IN COMBINATION WITH OTHER ANTIRETROVIRAL DRUGS, FOR THE TREATMENT OF HIV-1 INFECTION IN PEDIATRIC PATIENTS FROM AT LEAST 4 WEEKS TO LESS THAN 6 YEARS OF AGE
NDA 021721	SUPPL-28	NEW INDICATION	LEVOFLOXACIN	JANSSEN PHARMACEUTICALS INC	P	11/7/2011	4/27/2012	5.7	PROVIDES FOR THE TREATMENT AND PROPHYLAXIS OF PLAGUE DUE TO YERSINIA PESTIS IN ADULTS AND PEDIATRIC PATIENTS 6 MONTHS OF AGE AND OLDER
NDA 022116	SUPPL-12	PEDIATRIC	FOXAMPRENAVIR CALCIUM	VIIV HEALTHCARE CO	P	10/28/2011	4/27/2012	6.0	PROVIDES FOR A NEW DOSING REGIMEN FOR LEXIVA, WITH RITONAVIR, IN COMBINATION WITH OTHER ANTIRETROVIRAL DRUGS, FOR THE TREATMENT OF HIV-1 INFECTION IN PEDIATRIC PATIENTS FROM AT LEAST 4 WEEKS TO LESS THAN 6 YEARS OF AGE
NDA 022088	SUPPL-14	NEW PATIENT POPULATION	TEMSIROLIMUS	WYETH PHARMACEUTICALS INC	S	12/2/2011	5/30/2012	5.9	PROVIDES COMPLETED STUDY REPORT(S) AND PROPOSED LABELING TO ADDRESS THE PEDIATRIC WRITTEN REQUEST
NDA 022399	SUPPL-3	NEW INDICATION	GABAPENTIN ENACARBIL	GLAXO GROUP LTD	S	8/9/2011	6/6/2012	9.9	PROVIDES FOR THE MANAGEMENT OF POSTHERPETIC NEURALGIA
NDA 022212	SUPPL-3	NEW INDICATION	DIFLUPREDNATE	ALCON PHARMACEUTICALS LTD	S	12/24/2008	6/13/2012	41.7	PROVIDES FOR THE INDICATION OF TREATMENT OF ENDOGENOUS ANTERIOR UVEITIS
NDA 021446	SUPPL-28	NEW INDICATION	PREGABALIN	PF PRISM CV	P	12/20/2011	6/20/2012	6.0	PROVIDES FOR THE MANAGEMENT OF NEUROPATHIC PAIN ASSOCIATED WITH SPINAL CORD INJURY
NDA 021357	SUPPL-11	NEW INDICATION	GADOBNATE DIMEGLUMINE	BRACCO DIAGNOSTICS INC	S	9/6/2011	7/6/2012	10.0	PROVIDES FOR AN ADDITIONAL INDICATION OF MAGNETIC RESONANCE ANGIOGRAPHY (MRA) TO EVALUATE ADULTS WITH KNOWN OR SUSPECTED RENAL OR AORTO-ILIO-FEMORAL OCCLUSIVE VASCULAR DISEASE

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NDA 021358	SUPPL-9	NEW INDICATION	GADOBENATE DIMEGLUMINE	BRACCO DIAGNOSTICS INC	S	9/6/2011	7/6/2012	10.0	PROVIDES FOR AN ADDITIONAL INDICATION OF MAGNETIC RESONANCE ANGIOGRAPHY (MRA) TO EVALUATE ADULTS WITH KNOWN OR SUSPECTED RENAL OR AORTO-ILIO-FEMORAL OCCLUSIVE VASCULAR DISEASE
NDA 021752	SUPPL-30	NEW INDICATION	EMTRICITABINE/ TENOFOVIR DISOPROXIL FUMARATE	GILEAD SCIENCES INC	P	12/15/2011	7/16/2012	7.0	PROVIDES FOR THE USE IN COMBINATION WITH SAFER SEX PRACTICES, FOR PRE-EXPOSURE PROPHYLAXIS TO REDUCE THE RISK OF SEXUALLY ACQUIRED HIV-1 IN ADULTS AT HIGH RISK
NDA 017858	SUPPL-35	NEW INDICATION	TC-99M SULFUR COLLOID KIT	PHARMALUCENCE INC	S	10/21/2011	8/13/2012	9.8	PROVIDES FOR THE LOCALIZATION OF LYMPH NODES DRAINING A PRIMARY TUMOR IN PATIENTS WITH MELANOMA WHEN USED WITH A HAND-HELD GAMMA COUNTER
NDA 022108	SUPPL-7	NEW INDICATION	BUPROPION HYDROBROMIDE	VALEANT INTERNATIONAL SRL	S	7/15/2011	8/15/2012	13.1	PROVIDES FOR SEASONAL AFFECTIVE DISORDER (SAD)
NDA 021356	SUPPL-42	PEDIATRIC	TENOFOVIR DISOPROXIL FUMARATE	GILEAD SCIENCES INC	P	2/17/2012	8/16/2012	6.0	PROVIDES FOR TREATMENT OF CHRONIC HEPATITIS B IN PATIENTS 12 TO LESS THAN 18 YEARS OF AGE WEIGHING AT LEAST 35 KG
NDA 022577	SUPPL-2	PEDIATRIC	TENOFOVIR DISOPROXIL FUMARATE	GILEAD SCIENCES INC	P	7/13/2012	8/16/2012	1.1	PROVIDES FOR TREATMENT OF CHRONIC HEPATITIS B IN PATIENTS 12 TO LESS THAN 18 YEARS OF AGE WEIGHING AT LEAST 35 KG
NDA 200533	SUPPL-1	NEW INDICATION	TAPENTADOL	JANSSEN PHARMACEUTICALS INC	S	10/28/2011	8/28/2012	10.0	PROVIDES FOR THE MANAGEMENT OF NEUROPATHIC PAIN ASSOCIATED WITH DIABETIC PERIPHERAL NEUROPATHY
NDA 022083	SUPPL-16	MANUFACTURING CHANGE WITH CLINICAL DATA	RIVASTIGMINE	NOVARTIS PHARMACEUTICALS CORP	S	10/31/2011	8/31/2012	10.0	PROVIDES FOR THE TREATMENT OF MILD TO MODERATE DEMENTIA ASSOCIATED WITH PARKINSON'S DISEASE (PDD)
NDA 021135	SUPPL-24	PEDIATRIC	IRON SUCROSE	LUITPOLD PHARMACEUTICALS INC	S	9/7/2011	9/21/2012	12.5	PROVIDES FOR THE TREATMENT OF IRON DEFICIENCY ANEMIA IN PATIENTS WITH CHRONIC KIDNEY DISEASE (CKD)
NDA 022563	SUPPL-2	NEW INDICATION	CALCIPOTRIEN	STIEFEL LABORATORIES INC	S	11/29/2011	9/27/2012	10.0	PROVIDES FOR THE TOPICAL TREATMENT OF PLAQUE PSORIASIS OF THE SCALP AND BODY IN PATIENTS 18 YEARS AND OLDER
NDA 021476	SUPPL-26	NEW PATIENT POPULATION	ESZOPICLONE	SUNOVION PHARMACEUTICALS INC	P	4/10/2012	10/10/2012	6.0	CONTAINS FINAL STUDY REPORTS IN FULFILLMENT OF THE PEDIATRIC WRITTEN REQUEST OF APRIL 13, 2010
NDA 021660	SUPPL-31	NEW INDICATION	NAB PACLITAXEL	ABRAXIS BIOSCIENCE LLC	S	12/12/2011	10/11/2012	10.0	PROVIDES FOR FIRST-LINE TREATMENT OF LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER, IN COMBINATION WITH CARBOPLATIN, IN PATIENTS WHO ARE NOT CANDIDATES FOR CURATIVE SURGERY OR RADIATION THERAPY
NDA 021797	SUPPL-13	NEW PATIENT POPULATION	ENTECAVIR	BRISTOL MYERS SQUIBB	S	12/16/2011	10/12/2012	9.9	REVISES THE USE IN SPECIFIC POPULATIONS SECTION OF THE PACKAGE INSERT (SECTIONS 8.6 AND 8.8) TO INCLUDE DATA FROM STUDIES A1463109 (POST-LIVER TRANSPLANT POPULATION) AND A1463085 (BLACK/AFRICAN AMERICAN POPULATION)

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NDA 021797	SUPPL-14	NEW PATIENT POPULATION	ENTECAVIR	BRISTOL MYERS SQUIBB	S	12/16/2011	10/12/2012	9.9	REVISES THE USE IN SPECIFIC POPULATIONS SECTION OF THE PACKAGE INSERT (SECTIONS 8.6 AND 8.8) TO INCLUDE DATA FROM STUDIES A1463109 (POST-LIVER TRANSPLANT POPULATION) AND A1463085 (BLACK/AFRICAN AMERICAN POPULATION)
NDA 021798	SUPPL-14	NEW PATIENT POPULATION	ENTECAVIR	BRISTOL MYERS SQUIBB	S	12/16/2011	10/12/2012	9.9	REVISE THE USE IN SPECIFIC POPULATIONS SECTION OF THE PACKAGE INSERT (SECTIONS 8.6 AND 8.8) TO INCLUDE DATA FROM STUDIES A1463109 (POST-LIVER TRANSPLANT POPULATION) AND A1463085 (BLACK/AFRICAN AMERICAN POPULATION)
NDA 021798	SUPPL-16	NEW PATIENT POPULATION	ENTECAVIR	BRISTOL MYERS SQUIBB	S	12/16/2011	10/12/2012	9.9	REVISES THE USE IN SPECIFIC POPULATIONS SECTION OF THE PACKAGE INSERT (SECTIONS 8.6 AND 8.8) TO INCLUDE DATA FROM STUDIES A1463109 (POST-LIVER TRANSPLANT POPULATION) AND A1463085 (BLACK/AFRICAN AMERICAN POPULATION)
NDA 020563	SUPPL-123	NEW ROUTE OF ADMINISTRATION	INSULIN LISPRO	ELI LILLY AND CO	S	12/13/2011	10/14/2012	10.1	PROVIDES FOR THE INTRAVENOUS ROUTE OF ADMINISTRATION
NDA 022185	SUPPL-10	NEW INDICATION	BETAMETHASONE DIPROPIONATE/ CALCIPOTRIENE	LEO PHARMACEUTICAL PRODUCTS LTD	S	12/23/2011	10/17/2012	9.8	PROVIDES FOR THE ADDITIONAL INDICATION FOR PLAQUE PSORIASIS OF THE BODY
NDA 021427	SUPPL-41	NEW PATIENT POPULATION	DULOXETINE HYDROCHLORIDE	ELI LILLY AND CO	P	4/19/2012	10/18/2012	6.0	17 PROVIDES A RESPONSE TO THE PEDIATRIC WRITTEN REQUEST ISSUED ON JUNE 23, 2006, AND SUBSEQUENTLY AMENDED ON SEPTEMBER 22, 2009 AND NOVEMBER 2, 2009/ PROVIDES A RESPONSE TO THE AGENCY'S REQUIRED STUDY, UNDER THE PEDIATRIC RESEARCH EQUITY ACT, IN PEDIATRIC PATIENTS TO ASSESS AGES 7 TO
NDA 022406	SUPPL-1	NEW INDICATION	RIVAROXABAN	JANSSEN PHARMACEUTICALS INC	P	5/2/2012	11/2/2012	6.0	PROVIDE FOR THE TREATMENT OF DEEP VEIN THROMBOSIS, THE TREATMENT OF PULMONARY EMBOLISM, THE REDUCTION IN RISK FOR DEEP VEIN THROMBOSIS AND THE REDUCTION IN RISK FOR PULMONARY EMBOLISM
NDA 022406	SUPPL-2	NEW INDICATION	RIVAROXABAN	JANSSEN PHARMACEUTICALS INC	P	5/2/2012	11/2/2012	6.0	PROVIDE FOR THE TREATMENT OF DEEP VEIN THROMBOSIS, THE TREATMENT OF PULMONARY EMBOLISM, THE REDUCTION IN RISK FOR DEEP VEIN THROMBOSIS AND THE REDUCTION IN RISK FOR PULMONARY EMBOLISM
NDA 022406	SUPPL-3	NEW INDICATION	RIVAROXABAN	JANSSEN PHARMACEUTICALS INC	P	5/29/2012	11/2/2012	5.2	PROVIDE FOR THE TREATMENT OF DEEP VEIN THROMBOSIS, THE TREATMENT OF PULMONARY EMBOLISM, THE REDUCTION IN RISK FOR DEEP VEIN THROMBOSIS AND THE REDUCTION IN RISK FOR PULMONARY EMBOLISM
NDA 201152	SUPPL-4	PEDIATRIC	NEVIRAPINE	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	S	8/29/2011	11/8/2012	14.4	FOR THE TREATMENT OF HIV-1 INFECTION IN PEDIATRIC PATIENTS 6 TO LESS THAN 18 YEARS OF AGE
NDA 022291	SUPPL-8	NEW INDICATION	ELTROMBOPAG	GLAXOSMITHKLINE	P	5/24/2012	11/16/2012	5.8	TREATMENT OF THROMBOCYTOPENIA IN PATIENTS WITH CHRONIC HEPATITIS C TO ALLOW THE INITIATION AND MAINTENANCE OF INTERFERON-BASED THERAPY/ PROVIDES FOR THE ADDITION OF 100 MG STRENGTH TABLET

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NDA 020628	SUPPL-34	PEDIATRIC	SAQUINAVIR MESYLATE	HOFFMANN LA ROCHE INC	P	7/30/2010	11/30/2012	28.1	UPDATE THE LABELING WITH INFORMATION FROM PEDIATRIC STUDIES HIVNAT 017 AND NV20911
NDA 021785	SUPPL-11	PEDIATRIC	SAQUINAVIR MESYLATE	HOFFMANN LA ROCHE INC	P	7/30/2010	11/30/2012	28.1	UPDATE THE LABELING WITH INFORMATION FROM PEDIATRIC STUDIES HIVNAT 017 AND NV20911
NDA 021710	SUPPL-11	NEW INDICATION	CARBAMAZEPINE	VALIDUS PHARMACEUTICALS INC	S	4/1/2011	12/6/2012	20.2	PROVIDES FOR THE USE OF EQUETRO (CARBAMAZEPINE) EXTENDED-RELEASE CAPSULES FOR THE TREATMENT OF TRIGEMINAL NEURALGIA
NDA 021710	SUPPL-12	NEW INDICATION	CARBAMAZEPINE	VALIDUS PHARMACEUTICALS INC	S	4/1/2011	12/6/2012	20.2	PROVIDES FOR THE TREATMENT OF PARTIAL SEIZURES WITH COMPLEX SYMPTOMATOLOGY, GENERALIZED TONIC-CLONIC SEIZURES, AND MIXED SEIZURES
NDA 202022	SUPPL-2	NEW INDICATION	RILPIVIRINE	JANSSEN PRODUCTS LP	S	2/27/2012	12/7/2012	9.3	UPDATES THE LABELING WITH 96-WEEK, PHARMACOKINETIC, SAFETY AND EFFICACY DATA FROM TRIALS TMC278-C209 AND TMC278-C215 AND RESTRICTS THE INDICATION TO TREATMENT-NAÏVE ADULT PATIENTS WITH HIV RNA LESS THAN OR EQUAL TO 100,000 COPIES/ML AT START OF THERAPY
NDA 204200	ORIG-2	NEW INDICATION	EPINEPHRINE	JHP PHARMACEUTICALS LLC	P	3/7/2012	12/7/2012	9.0	PROVIDES FOR THE INDUCTION AND MAINTENANCE OF MYDRIASIS DURING OCULAR SURGERY
NDA 202379	SUPPL-5	NEW INDICATION	ABIRATERONE ACETATE	JANSSEN BIOTECH INC	P	6/14/2012	12/10/2012	5.9	INDICATED IN COMBINATION WITH PREDNISONE FOR THE TREATMENT OF PATIENTS WITH METASTATIC CASTRATION-RESISTANT PROSTATE CANCER
NDA 021087	SUPPL-62	NEW PATIENT POPULATION	OSELTAMIVIR PHOSPHATE	HOFFMANN LA ROCHE INC	P	6/22/2012	12/21/2012	6.0	EXPANDS THE PATIENT POPULATION TO INCLUDE PATIENTS 2 WEEKS TO ONE YEAR OF AGE, PROVIDE A TWICE DAILY DOSING RECOMMENDATION FOR TREATMENT AND PROVIDE SUMMARY SAFETY AND PHARMACOKINETIC INFORMATION
NDA 021246	SUPPL-45	NEW PATIENT POPULATION	OSELTAMIVIR PHOSPHATE	HOFFMANN LA ROCHE INC	P	6/21/2012	12/21/2012	6.0	EXPANDS THE PATIENT POPULATION TO INCLUDE PATIENTS 2 WEEKS TO ONE YEAR OF AGE, PROVIDE A TWICE DAILY DOSING RECOMMENDATION FOR TREATMENT AND PROVIDE SUMMARY SAFETY AND PHARMACOKINETIC INFORMATION

NDA Efficacy Supplements Approved (SE8)

APPLICATION NUMBER	SUBMISSION TYPE & NUMBER	SUPPLEMENT TYPE or SUBMISSION CLASS CODE	ESTABLISHED NAME	APPLICANT	PRIORITY REVIEW	RECEIPT DATE	APPROVAL DATE	TOTAL APPROVAL TIME (MONTHS)
NDA 022465	SUPPL-7	LABELING CHANGE WITH CLINICAL DATA	PAZOPANIB	GLAXOSMITHKLINE	S	3/16/2011	1/12/2012	9.9
NDA 021445	SUPPL-33	LABELING CHANGE WITH CLINICAL DATA	EZETIMIBE	MSD INTERNATIONAL GMBH	S	3/28/2011	1/24/2012	9.9
NDA 021687	SUPPL-39	LABELING CHANGE WITH CLINICAL DATA	EZETIMIBE	MSD INTERNATIONAL GMBH	S	3/24/2011	1/24/2012	10.1
NDA 020785	SUPPL-40	LABELING CHANGE WITH CLINICAL DATA	THALIDOMIDE	CELGENE CORP	S	10/1/2008	2/3/2012	40.1

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NDA 020363	SUPPL-38	LABELING CHANGE WITH CLINICAL DATA	FAMCICLOVIR	NOVARTIS PHARMACEUTICALS CORP	S	4/15/2011	2/9/2012	9.9
NDA 021098	SUPPL-19	LABELING CHANGE WITH CLINICAL DATA	DROSPIRENONE/ ETHINYL ESTRADIOL	BAYER HEALTHCARE PHARMACEUTICALS INC	S	4/13/2011	2/13/2012	10.1
NDA 022252	SUPPL-1	LABELING CHANGE WITH CLINICAL DATA	ESTRADIOL VALERATE/ DIENOGEST	BAYER HEALTHCARE PHARMACEUTICALS INC	S	4/15/2011	2/13/2012	10.0
NDA 022532	SUPPL-1	LABELING CHANGE WITH CLINICAL DATA	DROSPIRENONE/ ETHINYL ESTRADIOL/ LEVOMEFOLATE CALCIUM	BAYER HEALTHCARE PHARMACEUTICALS INC	S	4/13/2011	2/13/2012	10.1
NDA 022574	SUPPL-1	LABELING CHANGE WITH CLINICAL DATA	DROSPIRENONE/ ETHINYL ESTRADIOL/ LEVOMEFOLATE CALCIUM	BAYER HEALTHCARE PHARMACEUTICALS INC	S	4/13/2011	2/13/2012	10.1
NDA 022081	SUPPL-14	LABELING CHANGE WITH CLINICAL DATA	AMBRISENTAN	GILEAD SCIENCES INC	S	1/14/2010	2/15/2012	25.1
NDA 200678	SUPPL-4	LABELING CHANGE WITH CLINICAL DATA	SAXAGLIPTIN/ METFORMIN HYDROCHLORIDE	BRISTOL MYERS SQUIBB	S	5/18/2011	3/7/2012	9.7
NDA 022145	SUPPL-21	LABELING CHANGE WITH CLINICAL DATA	RALTEGRAVIR POTASSIUM	MERCK SHARP AND DOHME CORP	S	6/7/2011	3/28/2012	9.7
NDA 203045	SUPPL-1	LABELING CHANGE WITH CLINICAL DATA	RALTEGRAVIR	MERCK SHARP AND DOHME CORP	S	3/13/2012	3/28/2012	0.5
NDA 021536	SUPPL-37	LABELING CHANGE WITH CLINICAL DATA	INSULIN DETEMIR	NOVO NORDISK INC	S	5/31/2011	3/29/2012	10.0
NDA 022334	SUPPL-14	LABELING CHANGE WITH CLINICAL DATA	EVEROLIMUS/ SUNITINIB	NOVARTIS PHARMACEUTICALS CORP	S	7/11/2011	3/30/2012	8.6
NDA 022341	SUPPL-7	LABELING CHANGE WITH CLINICAL DATA	LIRAGLUTIDE	NOVO NORDISK INC	S	6/8/2011	4/6/2012	10.0
NDA 022145	SUPPL-23	LABELING CHANGE WITH CLINICAL DATA	RALTEGRAVIR POTASSIUM	MERCK SHARP AND DOHME CORP	S	7/12/2011	4/18/2012	9.2
NDA 203045	SUPPL-2	LABELING CHANGE WITH CLINICAL DATA	RALTEGRAVIR	MERCK SHARP AND DOHME CORP	S	3/13/2012	4/18/2012	1.2
NDA 021536	SUPPL-39	LABELING CHANGE WITH CLINICAL DATA	INSULIN DETEMIR	NOVO NORDISK INC	S	6/30/2011	4/27/2012	9.9
NDA 021842	SUPPL-10	LABELING CHANGE WITH CLINICAL DATA	METFORMIN/ PIOGLITAZONE HYDROCHLORIDE	TAKEDA GLOBAL RESEARCH DEVELOPMENT CENTER INC	S	6/1/2009	5/17/2012	35.5
NDA 021536	SUPPL-41	LABELING CHANGE WITH CLINICAL DATA	INSULIN DETEMIR	NOVO NORDISK INC	S	7/22/2011	5/18/2012	9.9
NDA 201280	SUPPL-2	LABELING CHANGE WITH CLINICAL DATA	LINAGLIPTIN	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	S	7/22/2011	5/22/2012	10.0
NDA 021330	SUPPL-13	LABELING CHANGE WITH CLINICAL DATA	NICOTINE POLACRILEX	GLAXOSMITHKLINE CONSUMER HEALTHCARE	S	3/25/2011	5/23/2012	14.0
NDA 022334	SUPPL-16	LABELING CHANGE WITH CLINICAL DATA	EVEROLIMUS/ SUNITINIB	NOVARTIS PHARMACEUTICALS CORP	S	11/3/2011	7/20/2012	8.5
NDA 020272	SUPPL-65	LABELING CHANGE WITH CLINICAL DATA	RISPERIDONE	JANSSEN PHARMACEUTICALS INC	S	5/19/2011	8/2/2012	14.5
NDA 020588	SUPPL-53	LABELING CHANGE WITH CLINICAL DATA	RISPERIDONE	JANSSEN PHARMACEUTICALS INC	S	5/19/2011	8/2/2012	14.5
NDA 021444	SUPPL-41	LABELING CHANGE WITH CLINICAL DATA	RISPERIDONE	JANSSEN PHARMACEUTICALS INC	S	5/19/2011	8/2/2012	14.5
NDA 021356	SUPPL-40	LABELING CHANGE WITH CLINICAL DATA	TENOFOVIR DISOPROXIL FUMARATE	GILEAD SCIENCES INC	S	10/12/2011	8/7/2012	9.9
NDA 022577	SUPPL-1	LABELING CHANGE WITH CLINICAL DATA	TENOFOVIR DISOPROXIL FUMARATE	GILEAD SCIENCES INC	S	7/13/2012	8/7/2012	0.8
NDA 201280	SUPPL-3	LABELING CHANGE WITH CLINICAL DATA	LINAGLIPTIN	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	S	10/14/2011	8/13/2012	10.0

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NDA 201280	SUPPL-4	LABELING CHANGE WITH CLINICAL DATA	LINAGLIPTIN	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	S	10/31/2011	8/13/2012	9.4
NDA 020899	SUPPL-15	LABELING CHANGE WITH CLINICAL DATA	HUMAN ALBUMIN MICROSPHERES	GE HEALTHCARE	S	3/23/2012	8/17/2012	4.8
NDA 022051	SUPPL-8	LABELING CHANGE WITH CLINICAL DATA	FLUTICASONE FUROATE	GLAXOSMITHKLINE	S	10/25/2011	8/21/2012	9.9
NDA 022264	SUPPL-5	LABELING CHANGE WITH CLINICAL DATA	PALIPERIDONE PALMITATE	JANSSEN PHARMACEUTICALS INC	S	1/25/2011	8/29/2012	19.1
NDA 021845	SUPPL-8	LABELING CHANGE WITH CLINICAL DATA	SILDENAFIL CITRATE	PFIZER INC	S	11/30/2011	8/30/2012	9.0
NDA 022473	SUPPL-3	LABELING CHANGE WITH CLINICAL DATA	SILDENAFIL CITRATE	PFIZER INC	S	11/30/2011	8/30/2012	9.0
NDA 020667	SUPPL-27	LABELING CHANGE WITH CLINICAL DATA	PRAMIPEXOLE DIHYDROCHLORIDE	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	S	11/2/2011	8/31/2012	10.0
NDA 022421	SUPPL-6	LABELING CHANGE WITH CLINICAL DATA	PRAMIPEXOLE DIHYDROCHLORIDE	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	S	11/4/2011	8/31/2012	9.9
NDA 022308	SUPPL-3	LABELING CHANGE WITH CLINICAL DATA	BESIFLOXACIN	BAUSCH AND LOMB INC	S	11/18/2011	9/18/2012	10.0
NDA 202343	SUPPL-1	LABELING CHANGE WITH CLINICAL DATA	SITAGLIPTIN/ SIMVASTATIN	MERCK SHARP AND DOHME CORP	S	11/22/2011	9/18/2012	9.9
NDA 201152	SUPPL-5	LABELING CHANGE WITH CLINICAL DATA	NEVIRAPINE	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	S	12/1/2011	9/28/2012	9.9
NDA 201280	SUPPL-5	LABELING CHANGE WITH CLINICAL DATA	LINAGLIPTIN	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	S	12/1/2011	9/28/2012	9.9
NDA 021290	SUPPL-22	LABELING CHANGE WITH CLINICAL DATA	BOSENTAN	ACTELION PHARMACEUTICALS LTD	S	12/8/2011	10/4/2012	9.9
NDA 021462	SUPPL-39	LABELING CHANGE WITH CLINICAL DATA	PEMETREXED DISODIUM	ELI LILLY AND CO	S	12/19/2011	10/17/2012	10.0
NDA 022029	SUPPL-11	LABELING CHANGE WITH CLINICAL DATA	METHYL SALICYLATE/ MENTHOL	HISAMITSU PHARMACEUTICAL CO INC	S	1/5/2012	11/5/2012	10.0
NDA 021344	SUPPL-20	LABELING CHANGE WITH CLINICAL DATA	FULVESTRANT	ASTRAZENECA PHARMACEUTICALS LP	P	6/28/2012	11/9/2012	4.4
NDA 021928	SUPPL-31	LABELING CHANGE WITH CLINICAL DATA	VARENICLINE	PFIZER INC	S	5/21/2012	12/11/2012	6.7
NDA 021658	SUPPL-6	LABELING CHANGE WITH CLINICAL DATA	CICLESONIDE	NYCOMED GMBH	S	2/17/2012	12/17/2012	10.0
NDA 021254	SUPPL-9	LABELING CHANGE WITH CLINICAL DATA	FLUTICASONE PROPIONATE/ SALMETEROL	GLAXOSMITHKLINE	S	6/26/2009	12/19/2012	41.8
NDA 022068	SUPPL-11	LABELING CHANGE WITH CLINICAL DATA	NILOTINIB	NOVARTIS PHARMACEUTICALS CORP	S	3/2/2012	12/20/2012	9.6

BLA Efficacy Supplements Approved

BLA NUMBER	SUBMISSION TYPE & NUMBER	SUPPLEMENT TYPE	PROPER NAME	APPLICANT	PRIORITY REVIEW	RECEIPT DATE	APPROVAL DATE	TOTAL APPROVAL TIME (MONTHS)	INDICATION
L 125104	SUPPL-576	EFFICACY	NATALIZUMAB	BIOGEN IDEC INC.	S	12/21/2010	1/20/2012	13.0	FOR INCLUSION OF LANGUAGE IN THE APPROVED LABEL DESCRIBING THE CLINICAL UTILITY OF AN ANTI-JCV ANTIBODY ASSAY FOR PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY (PML) RISK STRATIFICATION

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L 103628	SUPPL-5189	EFFICACY	INTERFERON BETA-1A	BIOGEN IDEC INC.	S	4/29/2011	2/27/2012	10.0	TO INCLUDE DOSE TITRATION LANGUAGE IN THE AVMEX PACKAGE INSERT AND PROVIDES FOR AN AVOSTARTGRIP TITRATION KIT, A 3-PACK OF DOSE LIMITING DEVICES TO BE USED WITH APPROVED AVONEX PRE-FILLED SYRINGES
L 103770	SUPPL-5161	EFFICACY	PALIVIZUMAB	MEDIMMUNE, LLC	S	6/10/2011	4/4/2012	9.8	FOR CONVERSION OF PACKAGE INSERT TO THE PHYSICIAN'S LABELING RULE (PLR) FORMAT AND TO UPDATE THE PACKAGE INSERT AND THE PATIENT PACKAGE INSERT WITH THE RESULTS OF STUDY CP116
L 125160	SUPPL-174	EFFICACY	CERTOLIZUMAB PEGOL	UCB, INC.	S	12/6/2011	4/17/2012	4.4	PROPOSES TO INCLUDE INFORMATION REGARDING THE EFFECT OF CIMZIA (CERTOLIZUMA PEGOL) ON VACCINES
L 125261	SUPPL-49	EFFICACY	USTEKINUMAB	JANSSEN BIOTECH, INC.	S	8/5/2011	5/31/2012	9.9	TO ADD LONGER-TERM SAFETY AND EFFICACY DATA TO THE STELARA PRESCRIBING INFORMATION
L 125084	SUPPL-225	EFFICACY	CETUXIMAB	IMCLONE LLC A WHOLLY-OWNED SUBSIDIARY OF ELI LILLY AND COMPANY	S	9/7/2011	7/6/2012	10.0	PROVIDES FOR MODIFICATIONS TO THE INDICATIONS AND USAGE SECTION OF LABELING TO STATE THAT ERBITUX IS INDICATED FOR THE TREATMENT OF PATIENTS WITH K-RAS MUTATION-NEGATIVE (WILD-TYPE), EGFR-EXPRESSING METASTATIC COLORECTAL CANCER AS DETERMINED BY FDA-APPROVED TESTS AND TO INCLUDE A NEW LIMITATION OF USE STATING THAT ERBITUX IS NOT INDICATED FOR TREATMENT OF K-RAS MUTATION-POSITIVE COLORECTAL CANCER. IN ADDITION, THIS SUPPLEMENT PROVIDES FOR A NEW INDICATION FOR ERBITUX FOR USE IN COMBINATION WITH FOLFIRI (IRINOTECAN, 5-FLUOROURACIL, LEUCOVORIN)
L 125156	SUPPL-76	EFFICACY	RANIBIZUMAB	GENENTECH, INC.	S	10/11/2011	8/10/2012	10.0	REVISIONS TO THE LUCENTIS PACKAGE INSERT TO DESCRIBE OBSERVATIONS OF PRE-INJECTION INTRAOCULAR PRESSURE INCREASE, OBSERVATIONS OF TEAR OF RETINAL PIGMENT EPITHELIUM AMONG PATIENTS WITH NEOVASCULAR AGE-RELATED MACULAR DEGENERATION (AMD), AND ADDITIONAL INFORMATION REGARDING PLACENTAL AND EMBRYO-FETAL DEVELOPMENT
L 125320	SUPPL-51	EFFICACY	DENOSUMAB	AMGEN, INC.	S	11/21/2011	9/20/2012	10.0	A NEW INDICATION FOR THE TREATMENT TO INCREASE BONE MASS IN MEN WITH OSTEOPOROSIS AT HIGH RISK OF FRACTURE
L 125387	SUPPL-4	EFFICACY	AFLIBERCEPT	REGENERON PHARMACEUTICALS, INC.	S	11/23/2011	9/21/2012	10.0	TREATMENT OF MACULAR EDEMA FOLLOWING CENTRAL RETINAL VEIN OCCLUSION (CRVO)
L 125057	SUPPL-232	EFFICACY	ADALIMUMAB	ABBOTT LABORATORIES	S	1/25/2011	9/28/2012	20.1	PROVIDES FOR HUMIRA (ADALIMUMAB) FOR INDUCING AND SUSTAINING CLINICAL REMISSION IN ADULT PATIENTS WITH MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS WHO HAVE HAD AN INADEQUATE RESPONSE TO IMMUNOSUPPRESSANTS SUCH AS CORTICOSTEROIDS, AZATHIOPRINE OR 6-MERCAPTOPYRINE

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L 125276	SUPPL-49	EFFICACY	TOCILIZUMAB	GENENTECH, INC.	S	12/13/2011	10/11/2012	10.0	PROVIDES FOR THE USE OF ACTEMRA (TOCILIZUMAB) FOR THE TREATMENT OF ADULT PATIENTS WITH MODERATELY TO SEVERELY ACTIVE RHEUMATOID ARTHRITIS WHO HAVE HAD AN INADEQUATE RESPONSE TO ONE OR MORE DISEASE-MODIFYING ANTI-RHEUMATIC DRUGS (DMARDS), REVISIONS TO THE HIGHLIGHTS AND WARNINGS SECTIONS OF THE PACKAGE INSERT REGARDING HYPERSENSITIVITY REACTIONS, AND A PROPOSED MODIFICATION TO THE APPROVED RISK EVALUATION AND MITIGATION STRATEGY (REMS)
L 103705	SUPPL-5367	EFFICACY	RITUXIMAB	GENENTECH, INC.	S	12/22/2011	10/19/2012	9.9	PROVIDE FOR THE USE OF RITUXAN AS A 90-MINUTE INFUSION FOR PREVIOUSLY UNTREATED FOLLICULAR NON-HODGKIN'S LYMPHOMA (NHL) AND DIFFUSE LARGE B-CELL LYMPHOMA (DLBCL) PATIENTS WHO HAVE TOLERATED THE STANDARD INFUSION OF RITUXAN AT CYCLE 1 AND FOR UPDATES TO SECTIONS 8.4 PEDIATRIC USE AND 6.3 CLINICAL TRIALS EXPERIENCE IN GRANULOMATOSIS WITH POLYANGIITIS (GPA) (WEGENER'S GRANULOMATOSIS) AND MICROSCOPIC POLYANGIITIS (MPA)
L 125085	SUPPL-239	EFFICACY	BEVACIZUMAB	GENENTECH, INC.	S	12/29/2011	10/26/2012	9.9	REVISE THE PACKAGE INSERT TO INCLUDE A LIMITATIONS OF USE STATEMENT IN THE INDICATIONS AND USAGE, METASTATIC COLORECTAL CANCER (1.1) SUBSECTION, TO INCLUDE DATA FROM STUDIES IN ADJUVANT COLORECTAL CANCER IN THE CLINICAL STUDIES SECTION, AND TO UPDATE THE ADVERSE REACTIONS, IMMUNOGENICITY (6.2) SUBSECTION
L 103950	SUPPL-5136	EFFICACY	ANAKINRA	SWEDISH ORPHAN BIOVITRUM AB (PUBL)	P	6/25/2012	12/21/2012	5.9	PROVIDES FOR THE USE OF ANAKINRA IN THE TREATMENT OF NEONATAL ONSET MULTI-SYSTEM INFLAMMATORY DISEASE (NOMID)