CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-802/S002

MEDICAL REVIEW

SEP 28 1999

Medical Officer's Safety Review Update
Division of Over-The-Counter Drug Products

NDA: 20-802, S-002
NAME: Excedrin® Migraine Tablets, Caplets, Geltabs
(Acetaminophen 250 mg/Aspirin 250 mg/Caffeine 65 mg)
SPONSOR: Bristol-Myers Products
1350 Liberty Ave.
Hillside, NJ 07207;
(908)851-6119
Steven J. Knapp
Senior Director, Global Regulatory Affairs
TYPE OF SUBMISSION: Commercial Pharmaceutical Efficacy Supplement
DATE OF SUBMISSION: December 18, 1998 **CDER**: December 18, 1998
DATE OF REVIEW: September 28, 1999
REVIEWER: Rosemarie Neuner, MD, MPH
PM: Mr. Kerry Rothschild, JD

Background

Since 1960 Bristol-Myers Products has marketed Excedrin® Extra-Strength (ES) as an over-the-counter (OTC) analgesic for the temporary relief of the pain of headache, sinusitis, colds, muscular aches, menstrual discomfort, toothaches and minor arthritis pain. In January 1998, the sponsor received agency approval to market this product separately as Excedrin® Migraine (NDA 20-802) for the new indication of pain of migraine headache without any change in the recommended dose range. The recommended dosage (for all formulations) is as follows: **Adults**: 2 (dosage form) with water every 6 hours while symptoms persist, not to exceed 8 (dosage form) in 24 hours, or as directed by a doctor. **Children**: Do not give to children under 12 unless directed by a doctor. Each dosage form of this combination analgesic compound contains the following 3 ingredients: acetaminophen 250 mg, aspirin 250 mg, and caffeine 65 mg.

In this supplemental submission the sponsor is now requesting that the migraine indication be expanded to include the relief of symptoms associated with migraines such as pain, nausea, sensitivity to light and sound, and difficulty in carrying out normal activities. In support of their request, the sponsor has resubmitted the results of 3 clinical studies (Studies GHBA-840, GHBA-841, and GHBA-842) that were reviewed in the original submission of NDA 20-802. (Refer to the original efficacy review dated 6/21/97 by Dr. Rudolph Widmark of HFD-550 and the consultative efficacy review dated 5/12/99 by Dr. Armando Oliva of HFD-120 for additional discussion of product efficacy.) This supplement also contained a summary of postmarketing data for Excedrin® ES for the 2-year pre-migraine approval period of January 1, 1996 to December 31, 1997, as well as postmarketing safety data for both Excedrin® ES and Excedrin® Migraine which was collected over the period of January 1, 1998 through September 30, 1998. The following is an updated review of the product's safety profile which includes a

discussion of the above postmarketing adverse event data, as well as a summary of the periodic adverse event reports that were submitted to NDA 20-802 for the periods of October 1, 1998 to December 31, 1998, January 1, 1999 to March 31, 1999 and April 1, 1999 to June 30, 1999.

I. Postmarketing Data Summary for Excedrin® ES During the Period of January 1, 1996 to December 31, 1997.

The sponsor estimates that a total of 3.5 billion tablets of Excedrin® ES were distributed during the 2-year pre-approval period from January 1, 1996 through December 31, 1997. There were a total of 1,678 adverse event reports attributed to the use of Excedrin® ES collected by the sponsor during this period. Sponsor's Table 2.1.1 found in Appendix I attached to the end of this review lists the distribution of adverse event reports by COSTART body systems that were reported during this period which occurred with an overall incidence >1%. The majority of the adverse events were classified under the following 3 body systems: body as a whole 32.7% (549/1,678); nervous system 26.5% (444/1,678); and digestive system 25.1% (421/1,678). The 6 listings which had frequencies >5% were: no drug effect 14.0% (234/549), nausea 8.8% (148/421), dyspepsia 7.9% (133/421), dizziness 7.3% (122/444), nervousness 6.9% (115/444), abdominal pain 6.3% (106/549), and insomnia 5.7% (96/444). (See Sponsor's Table 2.1.1 in Appendix I.)

Reviewer's Comments: *Review of the above summarized adverse event data is consistent with what one would expect for a combination product containing aspirin, acetaminophen and caffeine. Manufacturers who market products under the OTC monograph system are not required to report to the agency adverse events that have occurred with the use of their products. Thus this 2-year tabular summary of adverse events created by the sponsor is very helpful since it establishes a baseline safety profile for this product.*

II. Postmarketing Data Summary for Excedrin® ES and Excedrin® Migraine During the Period of January 1, 1998 to September 30, 1998.

The sponsor estimates that a total of 1.2 billion tablets of Excedrin® ES were distributed during the period of January 1, 1998 to September 30, 1998. There were a total of 933 adverse event reports attributed to the use of Excedrin® ES collected by the sponsor during this period. Adverse events for this period associated with the use of this product with an incidence of > 1% are shown listed in Sponsor's Table 2.1.1. (See Appendix I attached to the end of this review.) The majority of the adverse events were classified under the following 3 body systems: body as a whole 37.7% (352/933); nervous system 22.1% (207/933); and digestive system 23.9% (223/933). The 6 listings which had frequencies >5% were as follows: no drug effect 19.6% (183/933), nausea 9.6% (90/933), dyspepsia 6.2% (58/933), nervousness 6.2% (58/933), abdominal pain 5.6% (52/933), and dizziness 5.4% (50/933). (See Sponsor's Table

2.1.1 in Appendix 1.)

There was only 1 serious adverse event report submitted by the sponsor associated with the use of Excedrin® ES during this period. A 7-year old female with a history of headaches for 1 year, who was treated with 1 geltab of Excedrin® ES each time she had a headache as per her physician's recommendation, died following neurosurgery to correct a large brain aneurysm. The brain aneurysm was diagnosed after she had a headache that was more severe than usual. The neurosurgeon told the mother who reported the case that the aspirin in Excedrin® ES may have prolonged bleeding contributing to the child's death. The mother stated that she did not know that there was a "drug interaction precaution" on the product's label.

During this same time period, 527 million tablets of Excedrin® Migraine were distributed. The distribution of the 935 adverse events with incidences >1% that were collected in this period associated with the use of Excedrin® Migraine was very similar to that of Excedrin® ES with the majority occurring in the same 3 COSTART body systems: body as a whole 44.9% (420/935), nervous system 20.4% (191/935), and digestive system 19.7% (184/935). In contrast to only had 3 adverse event listings with frequencies >5% listed as follows: no drug effect 29.9% (280/935), nausea 8.4% (79/935), and nervousness 5.6% (52/935). (Refer to Sponsor's Table 2.1.1 in Appendix-I).

Medical Reviewer's Comments: Future cases such as the serious case report of the 7-year old female who died due to a misdiagnosed brain aneurysm may be prevented by the new warnings listed on the label of the Excedrin® Migraine product which serve as a reminder to consumers to seek medical attention if their headache pain is atypical. Although there are pediatric warnings on both product labels, there is no way to prevent off-label use of these products in children.

It is not surprising to this reviewer that the distribution of adverse events is similar for Excedrin® ES and Excedrin® Migraine since they are identical formulations that only differ in the indications for usage listed on their labels. What is surprising is that Excedrin® Migraine had as many adverse event reports as did Excedrin® ES during this period even though it was not marketed initially at the beginning of this 3-month period and far fewer tablets were sold. This may be explained by the availability of the 1-800 telephone number for consumer questions or complaints, the large volume of reports of no drug effect (280 reports) that were collected for Excedrin® Migraine following its introduction to the OTC market, or the phenomena of increased reporting of adverse events that is usually seen in the initial post-approval period. The distribution of adverse events for both products is similar to that of Excedrin® ES for the period of January 1996 to December 1997.

III. Postmarketing Data Summary for Excedrin® Migraine During the Period of October 1, 1998 to December 31, 1998.

The sponsor submitted 270 initial and 6 follow-up reports of adverse events associated with the use of Excedrin® Migraine collected during the period of October 1,

1998 to December 31, 1998. Seven (7) out of the 270 cases were considered to be serious in nature and are listed in Table 1 found on the following page. In many of these cases the trade name of the Excedrin® product used was unknown. Four (4) out of the 7 cases were accidental overdoses, 3 of which occurred in children (Report Numbers: M088720, M090172, M090174, and M090406). The remaining 3 case reports occurred in adults who developed tinnitus with permanent hearing loss (Report Numbers: M088663, M089066, and M089074). Two of these 3 cases occurred in individuals with histories of chronic use of Excedrin® (Report Numbers: M089066 and M089074). (Refer to the following table, Table 1, shown below.)

Table 1 - Serious Adverse Events Associated with the Use of Excedrin® Migraine During the Period of October 1, 1998 to December 31, 1998.

Report No.	Age/Sex	Adverse Event
M088663	40yo/F	Developed vertigo associated with buzzing and sudden loss of hearing S/P taking Excedrin® Migraine for a migraine. Symptoms persisted and the patient was hospitalized. Neurological work-up unremarkable. Treated with prednisone but hearing loss persisted.
M088720	23mos/M	Accidental overdose following the ingestion of 15 Excedrin® ES geltabs. Treated in the ER without sequelae.
M089066	62yo/F	H/O migraines for 35 years treated with 8 Excedrin® tablets a day. Developed persistent hearing loss of the left ear.
M089074	56yo/M	H/O taking 2-4 caplets of Excedrin® ES for 10 years for the treatment of headaches. Developed moderate hearing loss with ringing in bilateral ears which improved but persisted despite discontinuing the product.
M090172	20mos/M	Accidental overdose following the ingestion of 17 Excedrin® ES geltabs. Seen in the local ER with follow-up by physician without sequelae.
M090174	Unk/M	Reported to have "overdosed" on Excedrin® and Tylenol®. Developed trouble with his speech and right leg. No further information collected.
M090406	1yo/F	Mother reported that child may have taken at least 3 tablets of Excedrin®. No further information collected.

A linear listing of the remaining 263 nonserious case reports can be found in Appendix II at the end of this report. The overall distribution of the case reports were again similar to that seen previously for both this product and Excedrin® ES.

Medical Officer's Comments: There were no reports of unexpected adverse events collected during this postmarketing period for Excedrin® Migraine. Tinnitus and hearing loss are known side effects of salicylism. The current labeling for both Excedrin® products lists a warning to consumers to stop using the product if they experience ringing in the ears or loss of hearing. It may be useful to have a warning about not taking this product with other aspirin or acetaminophen containing products to further limit the risk of salicylism.

IV. Postmarketing Data Summary for Excedrin® Migraine During the Period of January 1, 1999 to March 31, 1999.

The sponsor submitted 243 initial report and 1 follow-up report of adverse events associated with the use of Excedrin® Migraine collected during the period of January 1, 1999 to March 31, 1999. Three (3) out of the 243 case reports were considered to be serious in nature and are listed in Table 2 shown below on the following page. All 3 serious case reports (Report Numbers: M092227, MM092781, and M093238) occurred in adults who developed tinnitus and decreased hearing. Only one individual (Report Number M092227) improved after she was treated with antibiotics for an ear infection. (See Table 2 listed below.)

Table 2 - Serious Adverse Events Associated with the Use of Excedrin® Migraine During the Period of January 1, 1999 to March 31, 1999.

Report No.	Age/Sex	Adverse Event
M092227	Unk/F	H/O flu-like symptoms and headache. Developed tinnitus and decreased hearing in bilateral ears following 2-weeks use of Excedrin® ES. She was also taking Theraflu , Tylenol Cold Tablets, Robitussin and Pediacare. She stopped all medications and was evaluated by her physician who treated her with a course of antibiotics. All symptoms resolved.
M092781	51yo/F	Chronic use of Excedrin® ES for the treatment of migraine headaches for many years. Developed intermittent tinnitus with decreased hearing in the left ear thought to be secondary to Excedrin® ES
M093238	29yo/F	H/O migraines who developed persistent tinnitus with decreased hearing in the right ear following 1 dose of Excedrin® Migraine.

A linear listing of the remaining 240 nonserious case reports can be found in Appendix III at the end of this report. Again the overall distribution of the case reports were similar to that seen previous for both this product and Excedrin® ES.

Medical Officer's Comments: Again there were no reports of unexpected adverse events collected during this postmarketing period for Excedrin® Migraine. As mentioned previously there is a consumer warning on the product's label for the signs and symptoms of ototoxicity associated with the use of aspirin containing products. It is interesting to note that 2 out of the 3 cases of tinnitus and decreased hearing were associated with the use of the Excedrin® ES product which does not have a consumer recommendation regarding duration for safe use for relief of headache pain. However, there is an OTC advisory panel recommendation under consideration to include a warning regarding the use of OTC analgesics for more than 10 days.

V. Postmarketing Data Summary for Excedrin® Migraine During the Period of April 1, 1999 to June 30, 1999.

The sponsor submitted 138 initial reports and no follow-up reports of adverse events associated with the use of Excedrin® Migraine collected during the period of April 1, 1999 to June 30, 1999. Two (2) out of the 138 cases were considered to be serious in nature and are listed in Table 3 shown below. One (Report Number 10039287) of the 2 cases was an accidental overdose in a 15-month old child. (See the following table, Table 3.) The other serious adverse event (Report Number M096312) was a case of hearing loss in a 44-year old female with a prior history of documented hearing loss after taking multiple doses of Excedrin® Migraine. (Refer to Table 2 shown below.)

Table 3 - Serious Adverse Events Associated with the Use of Excedrin® Migraine During the Period of April 1, 1999 to June 30, 1999.

Report No.	Age/Sex	Adverse Event
M096312	44yo/F	Prior history of documented "slight hearing loss" which got worse following the ingestion of 5-6 doses of Excedrin® Migraine to treat migraine headaches. Results of medical workup not known at the time of report.
10039287	15mos/M	Accidental overdose of unknown amount of Excedrin® ES. Treated in ER and discharged.

A linear listing of the remaining 136 nonserious case reports can be found in Appendix IV at the end of this report. Again the overall distribution of the case reports were similar to that seen previous for both this product and Excedrin® ES.

Medical Officer's Comments: As with the 2 other postmarketing quarters there were no reports of unexpected adverse events collected during this postmarketing period for Excedrin® Migraine. The 1 case of ototoxicity occurred in an individual who took multiple doses of the Excedrin® Migraine product. This risk should be diminished by the new labeling directions (i.e., a single dose) for the product.

Final Recommendations:

The overall safety profile for Excedrin® Migraine is similar to Excedrin® ES. The risk for developing ototoxicity when taking this product or Excedrin® ES with other aspirin containing products does exist, which may be reduced by the new labeling directions for single dosing of Excedrin® Migraine. A consumer warning against the concomitant use of multiple analgesic-containing products and additional consumer directions regarding chronicity of use should be considered as part of class labeling for OTC analgesic products.

/S/

Rosemarie Neuner, MD, MPH
Medical Reviewer, HFD-560

/S/

Linda M. Katz, MD, MPH
Deputy Dir., HFD-560

CC: NDA 20-802 File
HFD-120 Div. File
HFD-550 Div. File
HFD-560 Dir/Ganley
HFD-560 Dep Dir/Katz
HFD-560 Team Leader/Lumpkins
HFD-120 Team Leader/RLevin
HFD-560 MO/Neuner
HFD-560 PM/KRothschild

Attachment I

to

Safety Review Update

Table 2.1.1
Number and Percent[a] of Adverse Events (Overall Incidence >1%)
Sorted by Body System Organ Class

Adverse Events	Excedrin Migraine 1/98 - 9/98 N=935		Excedrin ES 1/98 - 9/98 N=933		Excedrin ES 1/96 - 12/97 N=1678	
Body System Adverse Events	**N**	**%[b]**	**N**	**%[b]**	**N**	**%[b]**
Body as a Whole	**420**	**44.9**	**352**	**37.7**	**549**	**32.7**
No Drug Effect	280	29.9	183	19.6	234	14.0
Overdose	0	0.0	4	0.4	45	2.7
Pain Abdomen	37	3.9	52	5.6	106	6.3
Headache	26	2.8	16	1.7	19	1.1
Edema (Face)	12	1.3	7	0.8	19	1.1
Reaction Aggravated	18	1.9	21	2.2	6	0.4
Nervous	**191**	**20.4**	**207**	**22.1**	**444**	**26.5**
Nervousness	52	5.6	58	6.2	115	6.9
Dizziness	31	3.3	50	5.4	122	7.3
Insomnia	28	2.9	31	3.3	96	5.7
Tremor	10	1.1	13	1.4	41	2.4
Paraesthesia	17	1.8	4	0.4	16	1.0
Digestive	**184**	**19.7**	**223**	**23.9**	**421**	**25.1**
Nausea	79	8.4	90	9.6	148	8.8
Dyspepsia	37	3.9	58	6.2	133	7.9
Diarrhea	29	3.1	21	2.3	39	2.3
Vomit	14	1.5	14	1.5	48	2.9
Skin	**50**	**5.3**	**32**	**3.4**	**72**	**4.3**
Pruritus	10	1.1	12	1.3	12	0.7
Sweat	10	1.1	6	0.6	20	1.2
Cardiovascular	**40**	**4.2**	**37**	**3.9**	**73**	**4.4**
Tachycardia	22	2.4	15	1.6	21	1.3
Palpitation	6	0.6	6	0.6	20	1.2
Special Senses	**21**	**2.2**	**30**	**3.2**	**45**	**2.7**
Tinnitus	7	0.7	20	2.1	24	1.4
Respiratory	**19**	**2.0**	**28**	**3.0**	**40**	**2.4**
Dyspnea	9	0.9	14	1.4	21	1.3
Urogenital	**6**	**0.6**	**12**	**1.3**	**11**	**0.7**
Metabolic & Nutritional	**2**	**0.2**	**4**	**0.4**	**6**	**0.4**
Hemic & Lymphatic	**1**	**0.1**	**6**	**0.6**	**10**	**0.6**
Musculoskeletal	**1**	**0.1**	**1**	**0.1**	**7**	**0.4**

[a] Underlined percentages identify events with a frequency >5%.

[b] Percent of total events

Attachment II

to

Safety Review Update

EXCEDRIN MIGRAINE
(apap + aspirin + caffeine)

NDA 20-802

Index of Serious Expected Initial and Follow-Up Reports

By Manufacturer File Number

Received 10/01/98 to 12/31/98
Initial Reports: Section IA; Follow-Up Reports: Section IB

MFR(CTU) FILE NO.	EXPANDED COSTART TERM	REPORTED TERM	REPORT TYPE
M088663	ASTHENIA	WEAKNESS ARM	INITIAL
	VOMITING	VOMIT	
	DIZZINESS	DIZZINESS	
	PARESTHESIA	TINGLING RIGHT ARM	
	AMBLYOPIA	BLURRED VISION	
	LACK OF DRUG EFFECT	LACK OF EFFECT	
	DEAFNESS	DEAFNESS	
	TINNITUS	RINGING RIGHT EAR	
M088720	OVERDOSE	ACCIDENTAL OVERDOSE BY CHILD	INITIAL
M089066	DEAFNESS	HEARING LOSS LEFT EAR	INITIAL
M089074	DEAFNESS	HEARING LOSS	INITIAL
	TINNITUS	RINGING IN EARS	
M090172	ACCIDENTAL OVERDOSE	ACCIDENTAL OVERDOSE	INITIAL
M090174	SPEECH DISORDER	SPEECH AFFECTED	INITIAL
	ACCIDENTAL OVERDOSE	ACCIDENTAL OVERDOSE	
M090406	OVERDOSE	ACCIDENTAL OVERDOSE BY CHILD	INITIAL

EXCEDRIN MIGRAINE
(apap + aspirin + caffeine)

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Index of Nonserious Initial and Follow-Up Reports

By Manufacturer File Number

Received 10/01/98 to 12/31/98
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MFR(CTU) FILE NO.	EXPANDED COSTART TERM	REPORTED TERM	REPORT TYPE
M079533	NAUSEA	NAUSEA	FOLLOW-UP
	PRURITUS	ITCHING	
	TACHYCARDIA	RAPID HEART RATE	
M086261	EPISTAXIS	NOSEBLEED	FOLLOW-UP
M087047	PARESTHESIA	NUMBNESS HAND	FOLLOW-UP
M087601	NAUSEA	NAUSEA	FOLLOW-UP
	LACK OF DRUG EFFECT	LACK OF EFFECT	
M087607	CHEST PAIN	CHEST HEAVINESS	FOLLOW-UP
	DYSPNEA	SHORTNESS OF BREATH	
M087608	ABDOMINAL PAIN	STOMACH PAIN	FOLLOW-UP
M087690	ABDOMINAL PAIN	ABDOMINAL CRAMPING	INITIAL
	GASTRITIS	GASTRIC DISCOMFORT	
	PARANOID REACTION	PARANOID	
	NERVOUSNESS	NERVOUS	
M087691	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M087793	ALLERGIC REACTION	ALLERGIC REACTION	INITIAL
M087795	ASTHENIA	WEAKNESS	INITIAL
	CHILLS	COLD	
	NAUSEA AND VOMITING	NAUSEA & VOMITING	

EXCEDRIN MIGRAINE
(apap + aspirin + caffeine)

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MFR(CTU) FILE NO.	EXPANDED COSTART TERM	REPORTED TERM	REPORT TYPE
M087801	INSOMNIA	SLEEPLESSNESS	INITIAL
	NERVOUSNESS	JITTERY	
M087804	AGGRAVATION REACTION	HEADACHE EXACERBATED	INITIAL
	HEADACHE	HEADACHE	
M087814	URTICARIA	HIVES	INITIAL
M087819	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M087822	HYPERTONIA	SPASM MUSCLE	INITIAL
	TREMOR	HAND TREMORS	
M087823	DYSPEPSIA	STOMACH UPSET	INITIAL
M087824	PAIN	JAW PAIN	INITIAL
	CIRCUMORAL PARESTHESIA	NUMBNESS LIP	
	NERVOUSNESS	JITTERY	
M087825	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M087826	NAUSEA	NAUSEA	INITIAL
	LACK OF DRUG EFFECT	LACK OF EFFECT	
	NERVOUSNESS	JITTERY	
M087848	VAGINAL HEMORRHAGE	VAGINAL BLEEDING	INITIAL
M087852	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M087855	NAUSEA	NAUSEA	INITIAL
	TREMOR	HAND SHAKINESS	
	NERVOUSNESS	NERVOUSNESS	

Bristol-Myers Squibb Company

EXCEDRIN MIGRAINE
(apap + aspirin + caffeine)

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MFR(CTU) FILE NO.	EXPANDED COSTART TERM	REPORTED TERM	REPORT TYPE
M087856	ECCHYMOSIS	BRUISING	INITIAL
M087858	NAUSEA	NAUSEA	INITIAL
	LACK OF DRUG EFFECT	LACK OF EFFECT	
M087978	NAUSEA AND VOMITING	NAUSEA & VOMITING	INITIAL
M087979	HEMORRHAGE	HEMATOMA	INITIAL
	ECCHYMOSIS	BRUISING	
M087980	FACE EDEMA	EYE SWOLLEN	INITIAL
M087982	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M087983	CHEST PAIN	CHEST TIGHTNESS	INITIAL
	DYSPNEA	SHORTNESS OF BREATH	
	LARYNGISMUS	THROAT CLOSING	
	LACK OF DRUG EFFECT	LACK OF EFFECT	
M088017	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M088024	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M088028	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M088030	NAUSEA	SICK TO STOMACH	INITIAL
M088164	DIZZINESS	DIZZINESS	INITIAL
	AMBLYOPIA	BLURRED VISION	

EXCEDRIN MIGRAINE
(apap + aspirin + caffeine)

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MFR(CTU) FILE NO.	EXPANDED COSTART TERM	REPORTED TERM	REPORT TYPE
M088165	HANGOVER EFFECT DIZZINESS ABNORMAL VISION	HANGOVER DIZZINESS SPOTS BEFORE EYES	INITIAL
M088167	DYSPEPSIA	UPSET STOMACH	INITIAL
M088169	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M088170	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M088171	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M088172	NAUSEA DIZZINESS SWEATING	NAUSEOUS DIZZY CLAMMY	INITIAL
M088173	INSOMNIA	SLEEPLESSNESS	INITIAL
M088175	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M088176	ASTHENIA	FEELING TIRED	INITIAL
M088177	NERVOUSNESS	NERVOUS	INITIAL
M088231	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M088233	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M088237	NERVOUSNESS	JITTERINESS	INITIAL

Bristol-Myers Squibb Company

EXCEDRIN MIGRAINE
(apap + aspirin + caffeine)

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MFR(CTU) FILE NO.	EXPANDED COSTART TERM	REPORTED TERM	REPORT TYPE
M088252	TACHYCARDIA	RAPID HEART BEATS	INITIAL
M088253	PARESTHESIA	NUMBNESS ARM	INITIAL
M088254	MALAISE	SICK FEELING	INITIAL
	DYSPEPSIA	UPSET STOMACH	
	NAUSEA	NAUSEA	
	NERVOUSNESS	SHAKINESS	
M088255	DYSPEPSIA	SICK TO HER STOMACH	INITIAL
	GASTRITIS	STOMACH IRRITATION	
	NAUSEA	NAUSEOUS	
M088256	ABDOMINAL PAIN	STOMACH PAIN	INITIAL
	GASTRITIS	GASTRIC DISCOMFORT	
M088349	DYSPEPSIA	UPSET STOMACH	INITIAL
	LACK OF DRUG EFFECT	LACK OF EFFECT	
M088354	NAUSEA	NAUSEOUS	INITIAL
	VOMITING	VOMIT	
M088356	ABDOMINAL PAIN	STOMACH PAIN	INITIAL
	DYSPEPSIA	HEARTBURN	
M088357	TACHYCARDIA	RAPID HEART RATE	INITIAL
	INSOMNIA	SLEEPLESSNESS	
M088359	ABDOMINAL PAIN	STOMACH ACHE	INITIAL

EXCEDRIN MIGRAINE
(apap + aspirin + caffeine)

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MFR(CTU) FILE NO.	EXPANDED COSTART TERM	REPORTED TERM	REPORT TYPE
M088362	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M088387	TINNITUS	RINGING IN EARS	INITIAL
M088388	DYSPEPSIA LACK OF DRUG EFFECT	UPSET STOMACH LACK OF EFFECT	INITIAL
M088390	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M088391	DYSPHAGIA PHARYNGITIS	CHOKING BURNING SENSATION IN THROAT	INITIAL
M088392	DYSPEPSIA	UPSET STOMACH	INITIAL
M088393	DYSPEPSIA	UPSET STOMACH	INITIAL
M088395	NERVOUSNESS	SHAKY FEELING	INITIAL
M088396	DYSPEPSIA STOMACH ULCER HEMORRHAGE	HEARTBURN BLEEDING ULCER	INITIAL
M088591	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M088600	NAUSEA VOMITING	NAUSEA VOMITING	INITIAL
M088601	DYSPEPSIA	UPSET STOMACH	INITIAL
M088602	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL

EXCEDRIN MIGRAINE
(apap + aspirin + caffeine)

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MFR(CTU) FILE NO.	EXPANDED COSTART TERM	REPORTED TERM	REPORT TYPE
M088604	URTICARIA	HIVES	INITIAL
M088605	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M088606	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M088626	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M088699	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M088700	AGGRAVATION REACTION HEADACHE LACK OF DRUG EFFECT	HEADACHE EXACERBATED HEADACHE LACK OF EFFECT	INITIAL
M088702	AGGRAVATION REACTION MIGRAINE	MIGRAINE EXACERBATED MIGRAINE	INITIAL
M088739	ASTHENIA BACK PAIN	WEAKNESS IN LEGS BACKACHE	INITIAL
M088740	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M088742	FACE EDEMA EDEMA PERIPHERAL PRURITUS RASH	SWOLLEN LIPS SWOLLEN HANDS ITCHY PALMS PALMS REDDENED	INITIAL
M088744	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M088747	MALAISE NAUSEA	SICK FEELING NAUSEOUS	INITIAL

EXCEDRIN MIGRAINE
(apap + aspirin + caffeine)

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MFR(CTU) FILE NO.	EXPANDED COSTART TERM	REPORTED TERM	REPORT TYPE
M088749	FACE EDEMA	LIP SWELLING	INITIAL
	MALAISE	SICK FEELING	
	SKIN DISORDER	SKIN SENSITIVE	
	URTICARIA	HIVES	
	ALLERGIC REACTION	ALLERGIC REACTION	
M088751	NAUSEA	NAUSEOUS	INITIAL
	PARESTHESIA	BURNING SENSATION	
M088752	INSOMNIA	SLEEPLESSNESS	INITIAL
M088784	MALAISE	SICK	INITIAL
M088785	NAUSEA	NAUSEA	INITIAL
	VOMITING	VOMITING	
M088786	TINNITUS	RINGING IN EARS	INITIAL
M088787	DIZZINESS	DIZZINESS	INITIAL
	TACHYCARDIA	INCREASED HEART RATE	
	NERVOUSNESS	NERVOUSNESS	
M088821	TACHYCARDIA	INCREASED HEART RATE	INITIAL
M088846	DYSPEPSIA	UPSET STOMACH	INITIAL
	NAUSEA	NAUSEA	
M088865	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M088866	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL

EXCEDRIN MIGRAINE
(apap + aspirin + caffeine)

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MFR(CTU) FILE NO.	EXPANDED COSTART TERM	REPORTED TERM	REPORT TYPE
M088876	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M088882	DEPERSONALIZATION	FEELING STRANGE	INITIAL
M089036	NERVOUSNESS	JITTERY	INITIAL
M089037	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M089038	MALAISE TACHYCARDIA	FEELING UNWELL HEART RACING	INITIAL
M089039	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M089040	INSOMNIA	SLEEPLESSNESS	INITIAL
M089043	ABDOMINAL PAIN DIARRHEA	STOMACH ACHE DIARRHEA	INITIAL
M089067	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M089069	PEPTIC ULCER	ULCER	INITIAL
M089070	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M089071	DYSPEPSIA	HEARTBURN	INITIAL
M089072	DYSPEPSIA	HEARTBURN	INITIAL
M089073	ASTHENIA NAUSEA	TIRED NAUSEA	INITIAL

EXCEDRIN MIGRAINE
(apap + aspirin + caffeine)

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MFR(CTU) FILE NO.	EXPANDED COSTART TERM	REPORTED TERM	REPORT TYPE
M089103	ABDOMINAL PAIN	ABDOMINAL CRAMPING	INITIAL
	DIARRHEA	DIARRHEA	
	NAUSEA	NAUSEA	
	PRURITUS	PRURITUS	
	RASH	REDDENED BLOTCHES	
M089105	ABDOMINAL PAIN	ABDOMINAL CRAMPING	INITIAL
	DIARRHEA	DIARRHEA	
	NAUSEA	NAUSEA	
M089172	ABDOMINAL PAIN	STOMACH CRAMPS	INITIAL
	VOMITING	VOMITING	
M089215	DIARRHEA	DIARRHEA	INITIAL
M089217	DIZZINESS	DIZZINESS	INITIAL
M089218	DYSPEPSIA	UPSET STOMACH	INITIAL
M089219	DIZZINESS	DIZZINESS	INITIAL
M089220	DRY MOUTH	DRY MOUTH	INITIAL
M089223	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M089226	DYSPEPSIA	UPSET STOMACH	INITIAL
	NERVOUSNESS	NERVOUS	
M089229	AGGRAVATION REACTION	NERVOUSNESS EXACERBATED	INITIAL
	NERVOUSNESS	NERVOUS	

EXCEDRIN MIGRAINE
(apap + aspirin + caffeine)

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MFR(CTU) FILE NO.	EXPANDED COSTART TERM	REPORTED TERM	REPORT TYPE
M089233	TINNITUS	POUNDING IN EARS	INITIAL
M089236	NERVOUSNESS	JITTERY	INITIAL
M089241	GASTROINTESTINAL DISORDER	GASTROINTESTINAL PROBLEMS	INITIAL
M089243	ASTHENIA NAUSEA	WEAK NAUSEOUS	INITIAL
M089244	ABDOMINAL PAIN DIARRHEA	STOMACH PAIN DIARRHEA	INITIAL
M089253	NAUSEA NERVOUSNESS	NAUSEA JITTERY	INITIAL
M089254	DYSPEPSIA	UPSET STOMACH	INITIAL
M089261	EAR PAIN	THROBBING EARS	INITIAL
M089264	NAUSEA	NAUSEA	INITIAL
M089265	NAUSEA VOMITING	NAUSEA VOMITING	INITIAL
M089267	LACK OF DRUG EFFECT NAUSEA	LACK OF EFFECT NAUSEA	INITIAL
M089269	TINNITUS	RINGING IN EARS	INITIAL
M089313	DYSPEPSIA	UPSET STOMACH	INITIAL

Bristol-Myers Squibb Company

EXCEDRIN MIGRAINE
(apap + aspirin + caffeine)

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MFR(CTU) FILE NO.	EXPANDED COSTART TERM	REPORTED TERM	REPORT TYPE
M089317	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M089319	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M089323	PALPITATION	PALPITATIONS	INITIAL
M089328	FACE EDEMA	SWELLING OF FACE AND TONGUE	INITIAL
	BLOODY DIARRHEA	BLOODY DIARRHEA	
	HEMATEMESIS	VOMITING BLOOD	
	EDEMA PERIPHERAL	SWELLING OF FOOT	
	URTICARIA	HIVES	
M089332	ABDOMINAL PAIN	ABDOMINAL CRAMPING	INITIAL
	ASTHENIA	SLUGGISHNESS	
	CHEST PAIN	CHEST PAIN	
	DIARRHEA	DIARRHEA	
	DIZZINESS	DIZZINESS	
M089337	DIZZINESS	DIZZINESS	INITIAL
	TREMOR	SHAKING	
M089338	DIZZINESS	DIZZINESS	INITIAL
	NERVOUSNESS	SHAKINESS	
M089339	NAUSEA	NAUSEA	INITIAL
	PHARYNGITIS	BURNING SENSATION IN THROAT	
M089340	MOVEMENT DISORDER	MOVEMENT DISORDER	INITIAL
	TACHYCARDIA	RAPID HEART RATE	
	NERVOUSNESS	SHAKY FEELING	

EXCEDRIN MIGRAINE
(apap + aspirin + caffeine)

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MFR(CTU) FILE NO.	EXPANDED COSTART TERM	REPORTED TERM	REPORT TYPE
M089344	DYSPEPSIA	UPSET STOMACH	INITIAL
	NAUSEA	SICK TO STOMACH	
	INSOMNIA	SLEEPLESSNESS	
	NERVOUSNESS	SHAKY FEELING	
M089356	GASTROINTESTINAL DISORDER	BOWEL DISORDER	INITIAL
M089407	NAUSEA	SICK TO STOMACH	INITIAL
	TACHYCARDIA	RAPID HEART RATE	
M089410	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M089416	PARESTHESIA	TINGLING SENSATION	INITIAL
M089421	FACE EDEMA	SWOLLEN LIPS	INITIAL
M089423	NAUSEA	NAUSEA	INITIAL
M089496	CONSTIPATION	CONSTIPATION	INITIAL
M089497	INSOMNIA	SLEEPLESSNESS	INITIAL
M089499	AGGRAVATION REACTION	HEADACHE EXACERBATED	INITIAL
	CHILLS	CHILLS	
	HEADACHE	HEADACHE	
M089692	HEADACHE	WITHDRAWAL HEADACHE	INITIAL
M089749	NAUSEA	NAUSEA	INITIAL
	VOMITING	VOMITING	

EXCEDRIN MIGRAINE
(apap + aspirin + caffeine)

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MFR(CTU) FILE NO.	EXPANDED COSTART TERM	REPORTED TERM	REPORT TYPE
M089751	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M089759	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M089760	ALOPECIA	THINNING HAIR	INITIAL
M089761	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M089767	URTICARIA	HIVES	INITIAL
M089779	LACK OF DRUG EFFECT NERVOUSNESS	LACK OF EFFECT SHAKINESS	INITIAL
M089783	MALAISE	SICK	INITIAL
M089784	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M089787	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M089788	URTICARIA	HIVES	INITIAL
M089809	PALPITATION	PALPITATIONS	INITIAL
M089813	MALAISE DIZZINESS	SICK DIZZY	INITIAL
M089824	PAIN UROGENITAL DISORDER	BLADDER PAIN BLADDER SPASM	INITIAL
M089827	VOMITING	VOMITING	INITIAL

EXCEDRIN MIGRAINE
(apap + aspirin + caffeine)

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MFR(CTU) FILE NO.	EXPANDED COSTART TERM	REPORTED TERM	REPORT TYPE
M089832	NERVOUSNESS	NERVOUS FEELING	INITIAL
M089839	INSOMNIA	SLEEPLESSNESS	INITIAL
M089840	DYSPEPSIA	UPSET STOMACH	INITIAL
M089844	DYSPEPSIA NERVOUSNESS	UPSET STOMACH JITTERY	INITIAL
M089864	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M089875	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M089877	PHARYNGITIS	BURNING SENSATION IN THROAT	INITIAL
M089878	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M089880	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M089882	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M089885	ABDOMINAL PAIN DYSPEPSIA	STOMACH PAIN ACID REFLUX	INITIAL
M089903	DYSPEPSIA	ACID REFLUX	INITIAL
M089905	TACHYCARDIA INSOMNIA	RAPID HEART BEATS SLEEPLESSNESS	INITIAL
M089907	NAUSEA	SICK TO STOMACH	INITIAL

EXCEDRIN MIGRAINE
(apap + aspirin + caffeine)

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MFR(CTU) FILE NO.	EXPANDED COSTART TERM	REPORTED TERM	REPORT TYPE
M089912	CHEST PAIN	CHEST PAINS	INITIAL
M089924	ABDOMINAL PAIN DYSPEPSIA	STOMACH HURT UPSET STOMACH	INITIAL
M089956	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M089958	NERVOUSNESS	JITTERY	INITIAL
M089959	HEPATITIS C	HEPATITIS C	INITIAL
M090065	INSOMNIA	SLEEPLESSNESS	INITIAL
M090070	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M090073	TREMOR INSOMNIA	TREMBLING SLEEPLESSNESS	INITIAL
M090079	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M090082	NAUSEA ANXIETY NERVOUSNESS	NAUSEA ANXIOUS SHAKINESS	INITIAL
M090085	NERVOUSNESS	NERVOUS	INITIAL
M090128	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M090148	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL

EXCEDRIN MIGRAINE
(apap + aspirin + caffeine)

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MFR(CTU) FILE NO.	EXPANDED COSTART TERM	REPORTED TERM	REPORT TYPE
M090150	ABDOMINAL PAIN PAIN	STOMACH BURNING CRAMPS	INITIAL
M090157	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M090159	MYASTHENIA	LEG WEAKNESS	INITIAL
M090246	INSOMNIA	SLEEPLESSNESS	INITIAL
M090248	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M090249	SOMNOLENCE	DROWSINESS	INITIAL
M090253	ABDOMINAL PAIN NAUSEA	STOMACH CRAMPS NAUSEA	INITIAL
M090254	MALAISE	SICK	INITIAL
M090255	NAUSEA LACK OF DRUG EFFECT	NAUSEA LACK OF EFFECT	INITIAL
M090261	ABDOMINAL PAIN DIARRHEA	STOMACH PAIN DIARRHEA	INITIAL
M090265	ABDOMINAL PAIN	STOMACH BURNING	INITIAL
M090275	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M090276	ABDOMINAL PAIN DYSPEPSIA NAUSEA	ABDOMINAL PAIN UPSET STOMACH NAUSEA	INITIAL

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MFR(CTU) FILE NO.	EXPANDED COSTART TERM	REPORTED TERM	REPORT TYPE
M090282	ASTHENIA	WEAK	INITIAL
	NAUSEA	NAUSEOUS	
	TREMOR	TREMORS	
	LACK OF DRUG EFFECT	LACK OF EFFECT	
M090298	ASTHENIA	WEAK	INITIAL
	ARRHYTHMIA	IRREGULAR HEART BEAT	
	NAUSEA	NAUSEOUS	
	TACHYCARDIA	RAPID HEART RATE	
M090334	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M090343	ASTHENIA	WEAKNESS	INITIAL
	DIZZINESS	DIZZINESS	
M090348	NAUSEA	NAUSEA	INITIAL
	LACK OF DRUG EFFECT	LACK OF EFFECT	
M090349	SYNCOPE	NEAR SYNCOPE	INITIAL
	DIZZINESS	DIZZY	
M090391	MALAISE	FEELING SICK	INITIAL
	SYNCOPE	NEAR SYNCOPE	
	NAUSEA	NAUSEOUS	
	DIZZINESS	DIZZY	
M090392	ABDOMINAL PAIN	BURNING IN STOMACH	INITIAL
	CHEST PAIN	CHEST BURNING	
	ANOREXIA	UNABLE TO EAT	

Attachment III

to

Safety Review Update

Bristol-Myers Squibb Company

EXCEDRIN MIGRAINE
(apap + aspirin + caffeine)

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MFR(CTU) FILE NO.	EXPANDED COSTART TERM	REPORTED TERM	REPORT TYPE
M091772	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M092720	CHEST PAIN	CHEST PAIN	INITIAL
M092721	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M092722	HEADACHE	HEADACHE	INITIAL
M092723	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M092724	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M092725	AGGRAVATION REACTION MIGRAINE LACK OF DRUG EFFECT	MIGRAINE EXACERBATED MIGRAINE HEADACHE LACK OF EFFECT	INITIAL
M092726	EDEMA PERIPHERAL RASH	SWOLLEN HANDS HAND REDNESS	INITIAL
M092728	ABDOMINAL PAIN DYSPEPSIA NAUSEA SOMNOLENCE LACK OF DRUG EFFECT	ABDOMINAL PAIN UPSET STOMACH NAUSEA DROWSINESS LACK OF EFFECT	INITIAL
M092730	NERVOUSNESS	JITTERY	INITIAL
M092731	ABDOMINAL PAIN DYSPEPSIA	PAIN IN STOMACH STOMACH UPSET	INITIAL

EXCEDRIN MIGRAINE
(apap + aspirin + caffeine)

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MFR(CTU) FILE NO.	EXPANDED COSTART TERM	REPORTED TERM	REPORT TYPE
M092732	ABDOMINAL PAIN	STOMACH ACHE	INITIAL
	DYSPEPSIA	STOMACH UPSET	
	VOMITING	VOMITING	
M092733	SINUSITIS	BURNING SINUSES	INITIAL
	EYE PAIN	BURNING EYES	
M092734	DYSPEPSIA	ACID INDIGESTION	INITIAL
M092735	ABDOMINAL PAIN	STOMACH ACHE	INITIAL
M092736	CHEST PAIN	CHEST TIGHTNESS	INITIAL
	FEVER	FEVER	
	DYSPEPSIA	HEARTBURN	
	ANXIETY	ANXIETY	
	COUGH INCREASED	COUGHING	
	PRURITUS	ITCHY SCALP	
	URTICARIA	HIVES	
	NERVOUSNESS	IRRITABILITY	
M092738	NAUSEA	NAUSEOUS	INITIAL
	DYSPNEA	SHORT OF BREATH	
	NERVOUSNESS	SHAKY FEELING	
M092739	ABDOMINAL PAIN	STOMACH ACHE	INITIAL
M092740	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M092741	DYSPEPSIA	UPSET STOMACH	INITIAL

EXCEDRIN MIGRAINE
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MFR(CTU) FILE NO.	EXPANDED COSTART TERM	REPORTED TERM	REPORT TYPE
M092742	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M092743	PARESTHESIA	TINGLING LIPS	INITIAL
	RHINITIS	NOSE EDEMA	
	PRURITUS	ITCHING FACE	
M092744	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M092745	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M092746	PHOTOSENSITIVITY REACTION	PHOTOSENSITIVITY	INITIAL
	NAUSEA	NAUSEA	
	LACK OF DRUG EFFECT	LACK OF EFFECT	
M092747	SKIN DISCOLORATION	REDNESS	INITIAL
M092748	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M092749	DIZZINESS	DIZZINESS	INITIAL
M092750	DIZZINESS	DIZZINESS	INITIAL
M092751	PERIPHERAL EDEMA	SWELLING HANDS	INITIAL
	LACK OF DRUG EFFECT	LACK OF EFFECT	
M092752	PHOTOSENSITIVITY REACTION	PHOTOSENSITIVITY	INITIAL
	NAUSEA	NAUSEA	
	VOMITING	VOMITING	
	EAR DISORDER	INTOLERANCE TO SOUND	
	LACK OF DRUG EFFECT	LACK OF EFFECT	

Bristol-Myers Squibb Company

EXCEDRIN MIGRAINE
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MFR(CTU) FILE NO.	EXPANDED COSTART TERM	REPORTED TERM	REPORT TYPE
M092753	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M092754	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M092755	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M092757	ABDOMINAL PAIN	STOMACH CRAMPS	INITIAL
M092758	ABDOMINAL PAIN	STOMACH CRAMPS	INITIAL
M092759	ABDOMINAL PAIN DIARRHEA	STOMACH CRAMPS DIARRHEA	INITIAL
M092760	EPISTAXIS	NOSEBLEEDS	INITIAL
M092761	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M092762	PAIN DIARRHEA DYSPEPSIA CIRCUMORAL PARESTHESIA ALOPECIA ABNORMAL VISION METRORRHAGIA	LEFT ARM PAIN DIARRHEA STOMACH PROBLEMS NUMBNESS FACE HAIR LOSS PERIPHERAL VISION BLURRINESS IRREGULAR MENSES	INITIAL
M092764	ABDOMINAL PAIN	STOMACH PAIN	INITIAL
M092765	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M092766	NAUSEA DIZZINESS	NAUSEA DIZZINESS	INITIAL

Bristol-Myers Squibb Company

EXCEDRIN MIGRAINE
(apap + aspirin + caffeine)

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MFR(CTU) FILE NO.	EXPANDED COSTART TERM	REPORTED TERM	REPORT TYPE
M092769	ALLERGIC REACTION	ALLERGIC REACTION	INITIAL
	CHEST PAIN	CHEST TIGHTNESS	
	FACE EDEMA	SWELLING FACE	
	DIZZINESS	LIGHTHEADED	
	VASODILATATION	HOT FEELING	
	HYPERVENTILATION	RAPID BREATHING	
M092773	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M092780	HEADACHE	REBOUND HEADACHE	INITIAL
M092784	DYSPEPSIA	STOMACH UPSET	INITIAL
M093303	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M093334	NERVOUSNESS	JITTERY	INITIAL
M093335	NERVOUSNESS	JITTERY	INITIAL
M093342	NAUSEA	NAUSEA	INITIAL
	VASODILATATION	FLUSHED FEELING	
	SWEATING	SWEATING	
M093345	SWEATING	SWEATING	INITIAL
	NAUSEA	NAUSEA	
M093363	ABDOMINAL PAIN	BURNING STOMACH	INITIAL
M093365	DEPERSONALIZATION	STONED	INITIAL
	NERVOUSNESS	JITTERY	

EXCEDRIN MIGRAINE
(apap + aspirin + caffeine)

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MFR(CTU) FILE NO.	EXPANDED COSTART TERM	REPORTED TERM	REPORT TYPE
M093399	DYSPHAGIA SWEATING	TABLET CAUGHT IN THROAT SWEATING	INITIAL
M093400	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M093403	GASTRITIS	STOMACH IRRITATION	INITIAL
M093404	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M093405	VOMITING	VOMITING	INITIAL
M093407	DYSPHAGIA	CHOKING	INITIAL
M093601	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M093628	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M093629	INSOMNIA	CAN NOT SLEEP AT NIGHT	INITIAL
M093630	DYSPEPSIA DIZZINESS	SICK TO HER STOMACH DIZZY	INITIAL
M093631	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M093632	DYSPEPSIA	INDIGESTION	INITIAL
M093633	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M093634	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL

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EXCEDRIN MIGRAINE
(apap + aspirin + caffeine)

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M093635	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M093636	CHEST PAIN NERVOUSNESS	CHEST PRESSURE NERVOUS	INITIAL
M093637	DIARRHEA	DIARRHEA	INITIAL
M093638	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M093639	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M093640	NERVOUSNESS	JITTERY	INITIAL
M093641	TINNITUS	RINGING IN EARS	INITIAL
M093643	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M093644	FACE EDEMA URTICARIA	LIPS SWOLLEN HIVES	INITIAL
M093645	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M093646	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M093647	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M093648	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M093649	DYSPHAGIA	DIFFICULTY SWALLOWING	INITIAL

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M093650	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M093942	EPISTAXIS	NOSEBLEED	INITIAL
	LACK OF DRUG EFFECT	LACK OF EFFECT	
M093955	CHEST PAIN	CHEST TIGHTNESS	INITIAL
M094088	ABDOMINAL PAIN	STOMACH BURNING	INITIAL
	DYSPEPSIA	UPSET STOMACH	
M094089	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M094094	MYASTHENIA	LEG WEAKNESS	INITIAL
	LACK OF DRUG EFFECT	LACK OF EFFECT	
M094099	ABDOMINAL PAIN	STOMACH CRAMPS	INITIAL
	LACK OF DRUG EFFECT	LACK OF EFFECT	
M094100	ABNORMAL STOOLS	UNUSUAL STOOLS	INITIAL
	URINE ABNORMALITY	DARK URINE	
M094142	NERVOUSNESS	JITTERY	INITIAL
M094146	ABDOMINAL PAIN	STOMACH CRAMPS	INITIAL
	MALAISE	SICK	
	SYNCOPE	FAINT FEELING	
M094148	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M094151	DYSPEPSIA	STOMACH UPSET	INITIAL

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M094153	INSOMNIA	SLEEPLESSNESS	INITIAL
	NERVOUSNESS	JITTERY	
M094157	FEVER	FEVER	INITIAL
	NAUSEA	NAUSEA	
	VOMITING	VOMIT	
	LACK OF DRUG EFFECT	LACK OF EFFECT	
M094163	SOMNOLENCE	SLEEPY	INITIAL
	TREMOR	SHAKES	
	LACK OF DRUG EFFECT	LACK OF EFFECT	
M094169	TREMOR	SHAKES	INITIAL
M094170	AGGRAVATION REACTION	HEADACHE EXACERBATED	INITIAL
	HEADACHE	HEADACHE	
	DIARRHEA	DIARRHEA	
	NAUSEA	NAUSEA	
	VOMITING	VOMITING	
	LACK OF DRUG EFFECT	LACK OF EFFECT	
M094173	TINNITUS	RINGING IN EARS	INITIAL
M094181	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M094184	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M094186	HYPERTENSION	HIGH BLOOD PRESSURE	INITIAL
	PRURITUS	ITCHING	

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M094188	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M094191	INCOORDINATION	INCOORDINATION	INITIAL
	TREMOR	SHAKING	
	LACK OF DRUG EFFECT	LACK OF EFFECT	
M094214	ABDOMINAL PAIN	STOMACH ACHE	INITIAL
M094218	INSOMNIA	SLEEPLESSNESS	INITIAL
M094239	ABDOMINAL PAIN	STOMACH HURT	INITIAL
	DYSPEPSIA	UPSET STOMACH	
	LACK OF DRUG EFFECT	LACK OF EFFECT	
M094241	TINNITUS	BUZZING IN EAR	INITIAL
M094255	ABDOMINAL PAIN	STOMACH CRAMPS	INITIAL
	NAUSEA	NAUSEA	
	LACK OF DRUG EFFECT	LACK OF EFFECT	
M094260	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M094263	AGGRAVATION REACTION	HEADACHE EXACERBATED	INITIAL
	FEVER	FEVER	
	HEADACHE	HEADACHE	
	NAUSEA	NAUSEA	
	DIZZINESS	DIZZY	
	TREMOR	SHAKING	
M094308	DIZZINESS	DIZZY	INITIAL

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M094313	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M094316	NERVOUSNESS	JITTERY	INITIAL
M094318	ABDOMINAL PAIN LACK OF DRUG EFFECT	STOMACH ACHE LACK OF EFFECT	INITIAL
M094391	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M094406	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M094411	ALLERGIC REACTION	ALLERGIC REACTION	INITIAL
M094439	TINNITUS	RINGING IN EARS	INITIAL
M094442	HEADACHE LACK OF DRUG EFFECT	REBOUND HEADACHE LACK OF EFFECT	INITIAL
M094443	TASTE PERVERSION	SALTY TASTE	INITIAL
M094447	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M094448	ACNE	PIMPLES	INITIAL
M094455	DIARRHEA	DIARRHEA	INITIAL
M094456	DIARRHEA	DIARRHEA	INITIAL
M094462	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL

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M094464	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M094466	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M094492	DIZZINESS DYSPNEA	DIZZY BREATHLESS	INITIAL
M094496	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M094499	HYPERGLYCEMIA INSOMNIA	INCREASED BLOOD SUGAR SLEEPLESSNESS	INITIAL
M094520	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M094524	URTICARIA	HIVES	INITIAL
M094531	TINNITUS	RINGING IN EARS	INITIAL
M094545	NERVOUSNESS	NERVOUSNESS	INITIAL
M094550	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M094560	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M094568	ASTHENIA NAUSEA DIZZINESS	WEAK NAUSEA DIZZY	INITIAL
M094569	NAUSEA	NAUSEA	INITIAL

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M094570	DIZZINESS	DIZZINESS	INITIAL
	LACK OF DRUG EFFECT	LACK OF EFFECT	
M094572	ANOREXIA	APPETITE ABSENT	INITIAL
	NAUSEA	NAUSEA	
	INSOMNIA	SLEEPLESSNESS	
M094576	NAUSEA	NAUSEA	INITIAL
	VOMITING	VOMITING	
	DIZZINESS	DIZZY	
	NERVOUSNESS	SHAKINESS	
M094577	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M094580	EUPHORIA	HIGH	INITIAL
M094585	DYSPEPSIA	UPSET STOMACH	INITIAL
	NAUSEA	NAUSEA	
M094586	NAUSEA	NAUSEA	INITIAL
M094591	ABDOMINAL PAIN	STOMACH ACHE	INITIAL
	DYSPEPSIA	HEARTBURN	
M094594	PRURITUS	PRURITUS	INITIAL
	RASH	RASH	
M094597	ASTHENIA	WEAKNESS	INITIAL
	DIZZINESS	DIZZY	

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M094620	HEADACHE	REBOUND HEADACHE	INITIAL
M094621	LACK OF DRUG EFFECT NERVOUSNESS	LACK OF EFFECT JITTERY	INITIAL
M094625	AGGRAVATION REACTION HEADACHE NERVOUSNESS	HEADACHE EXACERBATED HEADACHE SHAKINESS	INITIAL
M094633	ECCHYMOSIS	BRUISING	INITIAL
M094636	NECK RIGIDITY NAUSEA	STIFF NECK NAUSEA	INITIAL
M094642	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M094644	NERVOUSNESS	WIRED	INITIAL
M094646	CHEST PAIN	FUNNY FEELING CHEST	INITIAL
M094648	NERVOUSNESS	JITTERY	INITIAL
M094651	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M094653	NAUSEA VOMITING	NAUSEA VOMITING	INITIAL
M094654	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M094655	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL

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M094656	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M094658	ABDOMINAL PAIN	STOMACH ACHE	INITIAL
	NERVOUSNESS	JITTERY	
M094674	AGGRAVATION REACTION	HEADACHE EXACERBATED	INITIAL
	HEADACHE	HEADACHE	
	INSOMNIA	SLEEPLESSNESS	
M094677	DYSPEPSIA	SOUR STOMACH	INITIAL
M094731	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M094737	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M094738	STOMATITIS	LESION LIPS	INITIAL
	PRURITUS	ITCHING OVER BODY	
	RASH	RASH LEGS	
M094740	MALAISE	"FEEL FUNNY"	INITIAL
	LACK OF DRUG EFFECT	LACK OF EFFECT	
M094743	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M094753	ABDOMINAL PAIN	STOMACH HURT	INITIAL
M094759	TREMOR	TREMBLING	INITIAL
	TACHYCARDIA	INCREASED HEART RATE	
	NERVOUSNESS	JITTERY	

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M094760	DIARRHEA	DIARRHEA	INITIAL
M094761	NERVOUSNESS	SHAKINESS	INITIAL
M094762	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M094766	PREGNANCY USE DURING	PREGNANCY USE DURING	INITIAL
M094767	PALPITATION SYNCOPE PARESTHESIA	PALPITATIONS FEEL FAINT TINGLING HANDS	INITIAL
M094769	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M094770	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M094771	DYSPEPSIA	INDIGESTION	INITIAL
M094777	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M094784	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M094795	PALPITATION ANXIETY NERVOUSNESS	PALPITATIONS ANXIETY NERVOUSNESS	INITIAL
M094796	ABDOMINAL PAIN FLATULENCE	STOMACH CRAMPS BLOATING	INITIAL
M094801	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL

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M094803	PARESTHESIA	NUMBNESS HEAD	INITIAL
M094808	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M094809	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M094814	LACK OF DRUG EFFECT	LACK OF EFFECT	INITIAL
M094819	PALPITATION	PALPITATIONS	INITIAL
	DEPRESSION	DEPRESSED MOOD	
	NERVOUSNESS	NERVOUS	
M094821	PARESTHESIA	NUMBNESS TINGLING FINGER	INITIAL
	NERVOUSNESS	SHAKY FEELING	
M094833	ABDOMINAL PAIN	STOMACH ACHE	INITIAL
	ASTHENIA	TIRED	
	DYSPEPSIA	UPSET STOMACH	
	NAUSEA	NAUSEA	
M094943	ASTHENIA	TIRED	INITIAL
	ASTHENIA	WEAK	
	NERVOUSNESS	SHAKY FEELING	
M094945	FACE EDEMA	SWOLLEN FACE	INITIAL
	PRURITUS	ITCHY	
	URTICARIA	HIVES	
	LACK OF DRUG EFFECT	LACK OF EFFECT	
M094948	ABDOMINAL PAIN	STOMACH ACHE	INITIAL
	INSOMNIA	INSOMNIA	