U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

CFSAN Adverse Event Reporting System
Voluntary and Mandatory Reports on 5-Hour Energy, Monster Energy, and Rockstar Energy Drink
January 1, 2004, through October 23, 2012

Introduction

FDA's Center for Food Safety and Applied Nutrition (CFSAN) Adverse Event Reporting System (CAERS) collects reports about adverse health events and product complaints related to CFSAN-regulated products, including conventional foods, dietary supplements, and cosmetics. Based on a search of CAERS, this document summarizes the adverse events reported to FDA in connection with products under the labels 5-Hour Energy, Monster, and Rockstar between January 1, 2004 and October 23, 2012. These products are currently marketed as dietary supplements.

CAERS includes voluntary reports for cosmetics and conventional foods, and both voluntary and mandatory reports for dietary supplements. Mandatory reports are those required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act. Specifically, dietary supplement manufacturers, packers, and distributors must notify FDA if they receive reports about serious adverse events in connection with the use of their products. This law defines a serious adverse event as an adverse health-related event that is associated with the use of a dietary supplement and that results in death, a life-threatening experience, inpatient hospitalization, a persistent or significant disability or incapacity, a congenital anomaly or birth defect, or that requires, based on reasonable medical judgment, a medical or surgical intervention to prevent one of those outcomes. The requirement to report serious adverse events to FDA applies only to dietary supplements and not to beverages, other conventional foods, or cosmetics.

Medical officers with the agency's Dietary Supplement Program staff review all serious adverse events reported to FDA about dietary supplements as part of the normal process of assessment and categorization. In addition to these mandatory reports, the CAERS system also contains adverse events (both serious and non-serious) that are voluntarily reported to FDA by consumers and health care providers.

FDA encourages consumers and health care providers to report adverse events they believe may be related to FDA-regulated products to FDA's MedWatch Adverse Event Reporting Program (http://www.fda.gov/Safety/MedWatch/default.htm). FDA advises consumers to talk with their health care providers before using any product marketed as an "energy shot" or "energy drink."

Things You Should Know About Adverse Event Report Data

Individual adverse event reports about a particular product and the total number of adverse event reports for that product in CAERS only reflect information **AS REPORTED** and do not represent any conclusion by FDA about whether the product actually caused the adverse events. Because CAERS is constantly updated with new information, the number of reports for a given product and the content of individual reports may change over time.

Even with mandatory reporting of serious adverse events for dietary supplements, generally only a small fraction of adverse events associated with any product is reported. On the other hand, there may be duplicate reports in CAERS for the same adverse event because multiple people (such as an injured consumer and a health care provider who treated him or her) may have submitted reports.

There are important limitations to making inferences based on data from adverse event reports, such as those in CAERS.

- Reports to FDA do not necessarily include all relevant data, such as whether an individual also suffered from other medical conditions (such as cardiac disease) or took other supplements or medication at the same time.

- Reports may not include accurate or complete contact information for FDA to seek further information about the event, or complainants may choose not to participate in the follow-up investigation.

When important information is missing from a report, it is difficult for FDA to fully evaluate whether the product caused the adverse event or simply coincided with it. The fact that an adverse event happened after a person took a dietary supplement does not necessarily mean that the dietary supplement caused the adverse event.

CAERS Adverse Events Reports Allegedly Related to 5 Hour Energy

Search Terms: 5 Hour, Five Hour, 5Hour, FiveHour

The Center for Food Safety Adverse Event Reporting System (CAERS) is a post-market surveillance system that collects reports about events or problems that are allegedly related to CFSAN regulated products. In some reports, information in the reports cannot be verified for accuracy. Furthermore, in many reports, individuals may have used other products, and many products contain multiple ingredients which further complicates the evaluation of adverse event reports.

There is no certainty that a reported adverse event can be attributed to a particular product or ingredient. The number of adverse event reports in CAERS received by FDA and the adverse event report itself about a particular product only reflects information **AS REPORTED** and does not represent any conclusion by FDA regarding a causal relationship or association with the product or ingredient. Due to the continuous inclusion of new or updated information into the CAERS system, reports released from CAERS containing adverse event data may change over time.

Each report received by CAERS regarding an individual that experiences an adverse event is assigned a unique report number (Report #).

^ Additional dates indicate receipt of additional materials on report.

Report #	Received Date	Brand/ Product Name	Symptoms	Outcomes
79019	6/22/05	5 HOUR ENERGY CHASER	FEELING ABNORMAL, FLUSHING	NON-SERIOUS INJURIES/ ILLNESS
97070^	5/11/07 10/19/07	LIVING ESSENTIALS 5 HOUR BERRY FLAVOR ENERGY DRINK	FLUSHING, LETHARGY, DIZZINESS, ANXIETY, DYSPNOEA, BLOOD PRESSURE FLUCTUATION, HEART RATE ABNORMAL, DYSPNOEA, SHOCK, CHEST PAIN, SYNCOPE, VOMITING, DIARRHOEA, VISUAL DISTURBANCE, DEAFNESS, MOOD ALTERED, FATIGUE, PALPITATIONS, TACHYCARDIA, HEART RATE INCREASED, DEPRESSION, HEADACHE, ANAPHYLACTIC REACTION	LIFE THREATENING, VISITED AN ER, VISITED A HEALTH CARE PROVIDER, REQ. INTERVENTION TO PRVNT PERM. IMPRMNT.
100018	11/14/07	5 HOUR ENERGY ENERGY DRINK - BERRY FLAVOR	HYPERVENTILATION, DYSPHONIA, DISORIENTATION, TREMOR, DYSPNOEA, CONVULSION, POISONING	HOSPITALIZATION, LIFE THREATENING, VISITED AN ER, VISITED A HEALTH CARE PROVIDER, SERIOUS INJURIES/ ILLNESS

Report #	Received Date	Brand/ Product Name	Symptoms	Outcomes
102062^	3/10/08 12/17/09	LIVING ESSENTIALS 5 - HOUR ENERGY BERRY FLAVORED VITAMIN SUPPLEMENT	HEART RATE ABNORMAL, FAECAL INCONTINENCE, LOSS OF CONSCIOUSNESS, DIZZINESS, VOMITING, DISORIENTATION, AGGRESSION, LOSS OF CONSCIOUSNESS, LETHARGY, HEADACHE, TENDERNESS, DIZZINESS, VOMITING PROJECTILE, HEART RATE INCREASED, DRUG TOXICITY	LIFE THREATENING, HOSPITALIZATION
102367	3/10/08	LIVING ESSENTIALS 5 - HOUR ENERGY BERRY FLAVORED VITAMIN SUPPLEMENT	VOMITING, HEART RATE INCREASED	NON-SERIOUS INJURIES/ ILLNESS
103323	4/17/08	5 HOUR ENERGY SHOT	HAEMORRHAGE	NON-SERIOUS INJURIES/ ILLNESS
105441	7/23/08	LIVING ESSENTIALS 5 HOUR ENERGY	BLOOD PRESSURE FLUCTUATION, LETHARGY, DIZZINESS	NON-SERIOUS INJURIES/ ILLNESS
106752	9/29/08	INNOVATION VENTURES, LLC 5-HOUR ENERGY DRINK	NERVOUSNESS, NAUSEA, DIZZINESS, LOSS OF CONSCIOUSNESS, HALLUCINATION	NON-SERIOUS INJURIES/ ILLNESS
117103	8/5/09	5 HOUR ENERGY DRINK	ABNORMAL LOSS OF WEIGHT, SLEEP DISORDER, ANXIETY	NON-SERIOUS INJURIES/ ILLNESS
121679^	12/17/09 12/30/09 3/1/10	5 HOUR ENERGY	SNEEZING, FALL, VOMITING, CHEST PAIN, PULSE ABSENT, HEAD INJURY	VISITED A HEALTH CARE PROVIDER, DEATH
121680^	12/17/09 8/3/10	5 HOUR ENERGY	DEATH	DEATH
121681	12/17/09	5 HOUR ENERGY	ABORTION SPONTANEOUS	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)

Report #	Received Date	Brand/ Product Name	Symptoms	Outcomes
121748	12/29/09	5 HOUR ENERGY	DYSPNOEA, CHEST PAIN, SWELLING	VISITED AN ER, HOSPITALIZATION
124601	3/16/10	5 HOUR ENERGY BERRY FLAVOR	HYPERSENSITIVITY	VISITED AN ER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
124602	3/16/10	5 HOUR ENERGY BERRY	MALAISE, HEART RATE INCREASED, HEAT ILLNESS	VISITED AN ER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
124603	3/16/10	5 HOUR ENERGY	MYOCARDIAL INFARCTION	VISITED AN ER, VISITED A HEALTH CARE PROVIDER
124605	3/16/10	5 HOUR ENERGY	HOT FLUSH, HEART RATE INCREASED, ANXIETY, VISUAL IMPAIRMENT	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
124621	3/22/10	5 HOUR ENERGY	HYPERHIDROSIS, HEART RATE INCREASED, ANXIETY, DIZZINESS, FEAR	VISITED AN ER, NON-SERIOUS INJURIES/ ILLNESS
125698^	4/21/10 9/29/10	5 HOUR ENERGY	ARRHYTHMIA, SUPRAVENTRICULAR TACHYCARDIA, PALLOR, ANGINA PECTORIS	VISITED A HEALTH CARE PROVIDER
126785	5/19/10	5 HOUR ENERGY	FEAR, MALAISE	LIFE THREATENING
126786^	5/19/10 3/16/11	5 HOUR ENERGY	CONVULSION	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
126994	5/14/10	5 HOUR ENERGY	PALLOR, CHEST PAIN	LIFE THREATENING, VISITED AN ER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
126995	5/14/10	5 HOUR ENERGY	CARDIAC ARREST	LIFE THREATENING

Report #	Received Date	Brand/ Product Name	Symptoms	Outcomes
126996	5/14/10	5 HOUR ENERGY	CONVULSION	VISITED AN ER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
128525	7/28/10	5 HOUR ENERGY	DISORIENTATION, DIZZINESS, HEADACHE, CEREBROVASCULAR ACCIDENT, VISUAL ACUITY REDUCED	DISABILITY, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), HOSPITALIZATION
128651^	7/26/10	5 HOUR ENERGY	CONVULSION, SOMNOLENCE	HOSPITALIZATION
	3/16/11			
129061	8/13/10	5 HOUR ENERGY 5 HOUR ENERGY	VENTRICULAR ARRHYTHMIA, LOSS OF CONSCIOUSNESS, PNEUMONIA, CONVULSION, ACUTE RESPIRATORY FAILURE, ANOXIC ENCEPHALOPATHY	HOSPITALIZATION, DEATH
129370	8/20/10	5 HOUR ENERGY	PALPITATIONS, HYPERTENSION	HOSPITALIZATION
129372	8/26/10	5 HOUR ENERGY	DEATH	DEATH
131692	10/28/10	5 HOUR ENERGY	SOMNOLENCE	DEATH
131693^	10/28/10	5 HOUR ENERGY LEMON LIME	DEHYDRATION, PARALYSIS, FEELING JITTERY, TREMOR, MUSCLE CONTRACTIONS INVOLUNTARY, BLOOD POTASSIUM DECREASED, BLOOD CAFFEINE INCREASED	VISITED AN ER, LIFE THREATENING
	10/28/10	5 HOUR ENERGY EXTRA STRENGTH		
131933^	10/2/10	5 HOUR ENERGY - GRAPE	CONVULSION, BITE	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
	10/2/10	5 HOUR ENERGY - BERRY FLAVOR		

Report #	Received Date	Brand/ Product Name	Symptoms	Outcomes
132295	11/12/10	5-HOUR ENERGY POMEGRANA TE	DYSPHAGIA, JOINT DISLOCATION, PAIN, SWELLING, BRUXISM, JAW DISORDER	HOSPITALIZATION
132296	11/12/10	5-HOUR ENERGY BERRY	CONVULSION	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), VISITED AN ER, VISITED A HEALTH CARE PROVIDER
132297	11/12/10	5 HOUR ENERGY	CONVULSION	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
133099	12/2/10	5-HOUR ENERGY	RENAL FAILURE	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
133162	11/18/10	5 HOUR ENERGY DIETARY SUPPLEMENT ENERGY DRINK	HEART RATE ABNORMAL, LOSS OF CONSCIOUSNESS, DIZZINESS	VISITED A HEALTH CARE PROVIDER
134732	1/24/11	5-HOUR ENERGY BERRY	AURA, LOSS OF CONSCIOUSNESS, CONVULSION	VISITED AN ER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
134733	1/24/11	5-HOUR ENERGY BERRY	CARDIAC ARREST, CEREBROVASCULAR ACCIDENT, DIZZINESS, FEELING JITTERY, RESPIRATORY ARREST	DISABILITY, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), LIFE THREATENING, HOSPITALIZATION
134734	1/24/11	5-HOUR ENERGY POMEGRANA TE	CONVULSION, PAIN, TREMOR, MUSCLE TWITCHING	HOSPITALIZATION, VISITED AN ER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
136165	2/25/11	5 HOUR ENERGY	ANAPHYLACTIC SHOCK, DYSPNOEA, CHEST PAIN	LIFE THREATENING, VISITED AN ER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
136166	2/25/11	5 HOUR ENERGY	HYPOAESTHESIA, SUICIDAL IDEATION, PAIN, ACTIVITIES OF DAILY LIVING IMPAIRED	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), HOSPITALIZATION
136625^	3/8/11 6/27/11	5 HOUR ENERGY DRINK	HYPOAESTHESIA, BLOOD CREATINE PHOSPHOKINASE MB INCREASED	VISITED A HEALTH CARE PROVIDER, HOSPITALIZATION
137118	3/24/11	5 HOUR ENERGY	MYOCARDIAL INFARCTION, DEATH	DEATH

Report #	Received Date	Brand/ Product Name	Symptoms	Outcomes
137273	3/24/11	5 HOUR ENERGY	ANAPHYLACTIC SHOCK, URTICARIA, DYSPNOEA, LETHARGY, HYPERSOMNIA, ASTHENIA	LIFE THREATENING, VISITED AN ER, VISITED A HEALTH CARE PROVIDER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
138211	4/21/11	5 HOUR ENERGY EXTRA STRENGTH	RENAL IMPAIRMENT, FOETAL DISTRESS SYNDROME	LIFE THREATENING, CONGENITAL ANOMALY
139012	5/13/11	5 HOUR ENERGY	DEATH	DEATH
139013	5/13/11	5 HOUR ENERGY	DEATH	DEATH
139014	5/13/11	5 HOUR ENERGY EXTRA STRENGTH	ACUTE MYOCARDIAL INFARCTION, DIZZINESS, LOSS OF CONSCIOUSNESS, CEREBROVASCULAR ACCIDENT	HOSPITALIZATION, VISITED AN ER, LIFE THREATENING
139015	5/13/11	5 HOUR ENERGY	HYPOTENSION	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), HOSPITALIZATION
139016	5/13/11	5-HOUR ENERGY/ POMEGRANA TE	PAIN, HYPERHIDROSIS, CHEST DISCOMFORT, HEART RATE DECREASED	HOSPITALIZATION, VISITED AN ER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
139658	5/27/11	5 HOUR ENERGY ORANGE	PAIN, GENERALISED ERYTHEMA, HYPERTENSION, FEELING HOT, SWELLING FACE, HYPERSENSITIVITY, DYSPNOEA, URTICARIA, PALPITATIONS, PRURITUS, PO2 DECREASED, BREATH SOUNDS ABSENT	VISITED AN ER, LIFE THREATENING
140966	6/26/11	5 HOUR ENERGY	COMA, CEREBROVASCULAR ACCIDENT, HYPOAESTHESIA, VISUAL IMPAIRMENT	HOSPITALIZATION, DISABILITY
140968	6/27/11	5 HOUR ENERGY	VOMITING, HAEMATEMESIS, OESOPHAGEAL INJURY, INJURY	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), HOSPITALIZATION
142050	8/1/11	5 HOUR ENERGY	LETHARGY, ABDOMINAL PAIN, HEART RATE ABNORMAL	NON-SERIOUS INJURIES/ ILLNESS
142160	7/25/11	5 HOUR ENERGY	DEATH	DEATH

Report #	Received Date	Brand/ Product Name	Symptoms	Outcomes
142161	7/25/11	5 HOUR ENERGY	ABDOMINAL PAIN UPPER, NAUSEA, PAIN, BODY TEMPERATURE INCREASED, VOMITING, JAUNDICE, HEPATITIS, AMMONIA INCREASED, ALANINE AMINOTRANSFERASE INCREASED, BLOOD BILIRUBIN INCREASED, ASPARTATE AMINOTRANSFERASE INCREASED, BLOOD BILIRUBIN INCREASED, GAMMA-GLUTAMYLTRANSFERASE INCREASED	VISITED AN ER, HOSPITALIZATION
142457	8/12/11	5 HOUR ENERGY	COLD SWEAT, DIZZINESS, BLOOD PRESSURE DECREASED, LOSS OF CONSCIOUSNESS, CONVULSION, MYOCARDIAL INFARCTION, DYSPNOEA	HOSPITALIZATION, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), LIFE THREATENING
142772	6/13/11	LIVING ESSENTIALS/ BERRY FLAVORED 5-HOUR ENERGY DRINK	VOMITING, BURNING SENSATION	HOSPITALIZATION, VISITED A HEALTH CARE PROVIDER, VISITED AN ER
143074	9/1/11	5 HOUR ENERGY	CEREBROVASCULAR ACCIDENT, CEREBRAL HAEMORRHAGE	LIFE THREATENING, HOSPITALIZATION
143643	9/15/11	5 HOUR ENERGY LEMON LIME	HYPERSENSITIVITY	LIFE THREATENING
143644	9/15/11	5 HOUR ENERGY POMEGRANA TE	HYPERSENSITIVITY	VISITED AN ER, LIFE THREATENING
143645	9/15/11	5-HOUR ENERGY	ACQUIRED IMMUNODEFICIENCY SYNDROME	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
144858	10/24/11	5 HOUR ENERGY	MYOCARDIAL INFARCTION	DEATH
146464	11/22/11	LIVING ESSENTIALS 5 HOUR ENERGY POMEGRANA TE ENERGY SHOT	ABDOMINAL PAIN, ABDOMINAL PAIN UPPER	NON-SERIOUS INJURIES/ ILLNESS
147296	12/30/11	5 HOUR ENERGY	HOSPITALISATION	HOSPITALIZATION

Report #	Received Date	Brand/ Product Name	Symptoms	Outcomes
147297	12/30/11	5-HOUR ENERGY	DEATH	DEATH
148558	2/6/12	5 HOUR ENERGY	MYOCARDIAL INFARCTION	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
148559^	2/6/12	5 HOUR ENERGY ORANGE	DYSPNOEA, TREMOR, HYPOAESTHESIA, CHEST PAIN	HOSPITALIZATION, VISITED AN ER, NON-SERIOUS INJURIES/ ILLNESS
	2/6/12	5 HOUR ENERGY POMEGRANA TE		
148696	2/10/12	5 HOUR ENERGY	CEREBROVASCULAR ACCIDENT, CARDIOMEGALY, HEART RATE INCREASED	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
148905	2/14/12	5 HOUR ENERGY	VOMITING	HOSPITALIZATION
149591	3/2/12	5 HOUR ENERGY BERRY	CONVULSION	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
149601	3/2/12	5 HOUR ENERGY BERRY	CONVULSION	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
149603	3/2/12	5 HOUR ENERGY BERRY	CONVULSION	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
149857^	3/9/12	5 HOUR ENERGY BERRY	MYOCARDIAL INFARCTION, CHEST PAIN	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), HOSPITALIZATION, VISITED AN ER, VISITED A HEALTH CARE PROVIDER
	4/18/12			
150092	3/16/12	5-HOUR ENERGY	RENAL DISORDER, JAUNDICE, TONGUE DISCOLOURATION	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), HOSPITALIZATION
150093	3/16/12	5 HOUR ENERGY BERRY	ANAPHYLACTIC REACTION, DYSPNOEA, URTICARIA	HOSPITALIZATION, VISITED AN ER, LIFE THREATENING

Report #	Received Date	Brand/ Product Name	Symptoms	Outcomes
150422	3/23/12	5 HOUR ENERGY	MYOCARDIAL INFARCTION, CIRCULATORY COLLAPSE	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
150936^	4/6/12	5 HOUR ENERGY EXTRA STRENGTH GRAPE	FATIGUE, MIGRAINE, DIZZINESS, NAUSEA, AGITATION, DEPENDENCE, MALAISE, DRUG WITHDRAWAL SYNDROME, FEELING ABNORMAL	HOSPITALIZATION
	4/6/12	5 HOUR ENERGY BERRY		
150937	4/6/12	5 HOUR ENERGY	CONVULSION	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
152471	5/15/12	FIVE HOUR ENERGY BOOSTER	DIARRHOEA, VOMITING, CHROMATURIA, JAUNDICE, PRURITUS, ANOREXIA, BILIARY SPHINCTEROTOMY, CHOLESTASIS, GALLBLADDER DISORDER, PANCREATIC DISORDER	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), HOSPITALIZATION
153005	6/1/12	5 HOUR ENERGY BERRY	ABDOMINAL PAIN UPPER, VOMITING, BACK PAIN, DIARRHOEA HAEMORRHAGIC, GASTRIC DISORDER, GASTRIC HAEMORRHAGE	HOSPITALIZATION, VISITED AN ER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
154568^	7/19/12	5-HOUR ENERGY POMEGRANA TE	LOSS OF CONSCIOUSNESS, HEAD INJURY, DIZZINESS, CONCUSSION, TREMOR, CONVULSION, BRAIN OEDEMA	VISITED AN ER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
	8/31/12			
154669^	7/24/12	5-HOUR ENERGY GRAPE	ERYTHEMA, PRURITUS, TONGUE OEDEMA, URTICARIA, OBSTRUCTIVE AIRWAYS DISORDER, DYSPHAGIA	VISITED AN ER, LIFE THREATENING
	10/17/12			
155222	8/7/12	5-HOUR ENERGY	COELIAC DISEASE	HOSPITALIZATION
155230	8/7/12	5 HOUR ENERGY	COMPLETED SUICIDE	DEATH

Report #	Received Date	Brand/ Product Name	Symptoms	Outcomes
156365^	9/10/12 9/28/12	5 HOUR ENERGY	HOSPITALISATION	HOSPITALIZATION
156366	9/10/12	5 HOUR ENERGY BERRY	FEELING ABNORMAL, SOMNOLENCE, LOSS OF CONSCIOUSNESS, COMA, DRUG TOXICITY	HOSPITALIZATION, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
156368	9/10/12	5 HOUR ENERGY	HEART RATE IRREGULAR, MYOCARDIAL INFARCTION	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
157207	10/1/12	5 HOUR ENERGY	SUDDEN CARDIAC DEATH, FATIGUE, LOSS OF CONSCIOUSNESS, MYOCARDIAL INFARCTION	DEATH
157210	9/28/12	5-HOUR ENERGY	METABOLIC ACIDOSIS, SYSTEMIC INFLAMMATORY RESPONSE SYNDROME, BRONCHOSPASM, HEPATIC ENZYME INCREASED, INSOMNIA, MYOGLOBIN BLOOD INCREASED, MANIA	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
158006	10/22/12	5-HOUR ENERGY	MOTOR DYSFUNCTION, CONVULSION	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
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CAERS Adverse Events Reports Allegedly Related to Monster

Search Terms: Monster

The Center for Food Safety Adverse Event Reporting System (CAERS) is a post-market surveillance system that collects reports about events or problems that are allegedly related to CFSAN regulated products. In some reports, information in the reports cannot be verified for accuracy. Furthermore, in many reports, individuals may have used other products, and many products contain multiple ingredients which further complicates the evaluation of adverse event reports.

There is no certainty that a reported adverse event can be attributed to a particular product or ingredient. The number of adverse event reports in CAERS received by FDA and the adverse event report itself about a particular product only reflects information **AS REPORTED** and does not represent any conclusion by FDA regarding a causal relationship or association with the product or ingredient. Due to the continuous inclusion of new or updated information into the CAERS system, reports released from CAERS containing adverse event data may change over time.

Each report received by CAERS regarding an individual that experiences an adverse event is assigned a unique report number (Report #).

*Previous versions of this document may include CAERS reports 150942 and 150496. Since we received two CAERS reports for the same individual, we have merged them into a single CAERS report (150942).

^ Additional dates indicate receipt of additional materials on report.

Report #	Received Date	Brand/Product Name	Symptoms	Outcomes
66354	2/4/04	MONSTER ENERGY ENERGY SUPPLEMENT DRINK	ABDOMINAL PAIN UPPER, RETCHING, VOMITING, DIARRHOEA, WEIGHT DECREASED, DIZZINESS, HOSPITALISATION	LIFE THREATENING, HOSPITALIZATION
71234	8/11/04	MONSTER ENERGY DRINK	MYOCARDIAL INFARCTION, ELECTROCARDIOGRAM ST SEGMENT ELEVATION, HOSPITALISATION	HOSPITALIZATION, LIFE THREATENING
75388	1/10/05	MONSTER BEVERAGE CO MONSTER ENERGY	FATIGUE	VISITED A HEALTH CARE PROVIDER
78111	4/6/05	HANSENS MONSTER ENERGY DRINK	PHARYNGITIS, DIZZINESS	NON-SERIOUS INJURIES/ ILLNESS
86237	3/22/06	MONSTER ENERGY DRINK	TREMOR, DYSPNOEA, VOMITING, CHEST PAIN, TREMOR, RHABDOMYOLYSIS, MYOCLONUS	HOSPITALIZATION, VISITED AN ER, LIFE THREATENING
111857	4/7/09	MONSTER ENERGY DRINK	DEATH	DEATH
112784	4/7/09	MONSTER BLUE LOW CARB ENERGY DRINK	NAUSEA, THROAT IRRITATION	NON-SERIOUS INJURIES/ ILLNESS

Report #	Received Date	Brand/Product Name	Symptoms	Outcomes
113068	5/7/09	MONSTER ENERGY DRINK	BIPOLAR DISORDER, PSYCHOTIC DISORDER, PERSONALITY DISORDER, SUICIDAL IDEATION	HOSPITALIZATION
116885	6/2/09	JAVA MONSTER PLUS ENERGY ENERGY DRINK RUSSIAN FLAVOR	GASTROENTERITIS SALMONELLA, MALAISE, VOMITING, BACK PAIN, HEADACHE, ABDOMINAL PAIN, COUGH, DIARRHOEA	NON-SERIOUS INJURIES/ ILLNESS
128536	7/28/10	MONSTER ENERGY DRINK	FATIGUE, INFLUENZA LIKE ILLNESS, MEMORY IMPAIRMENT, MIGRAINE, ANGINA PECTORIS, PALPITATIONS, EYE PAIN, MALAISE, DYSURIA, NEUROPATHY PERIPHERAL, NIGHT SWEATS, DECREASED APPETITE, ASTHENIA, PAIN, INSOMNIA, HEADACHE, FLUSHING, VISUAL ACUITY REDUCED	LIFE THREATENING, HOSPITALIZATION
130690	10/5/10	MONSTER ENERGY DRINK	DYSPNOEA, POLLAKIURIA, BLOOD POTASSIUM DECREASED	VISITED AN ER, HOSPITALIZATION
132041^	11/12/10 6/21/12	MONSTER NITROUS	DEATH	DEATH
133771	12/8/10	JAVA MONSTER MEAN BEAN COFFEE FLAVORED ENERGY DRINK	VOMITING, ABDOMINAL PAIN	NON-SERIOUS INJURIES/ ILLNESS
142050	8/1/11	MONSTER ENERGY	LETHARGY, ABDOMINAL PAIN, HEART RATE ABNORMAL	NON-SERIOUS INJURIES/ ILLNESS
143117	8/1/11	MONSTER/LOW CARB ENERGY DRINK	CONJUNCTIVITIS	VISITED A HEALTH CARE PROVIDER, NON-SERIOUS INJURIES/ ILLNESS
144780	4/14/11	MONSTER HIT MAN ENERGY DRINK	NAUSEA, DIZZINESS, VOMITING, HEART RATE ABNORMAL, BLOOD PRESSURE FLUCTUATION	NON-SERIOUS INJURIES/ ILLNESS

Report #	Received Date	Brand/Product Name	Symptoms	Outcomes
145133	10/26/11	MONSTER DRINK	MUSCLE SPASMS, ABASIA, DIZZINESS, MUSCULOSKELETAL STIFFNESS, DYSPNOEA, PAIN IN EXTREMITY	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
145546	11/10/11	MONSTER ENERGY DRINK	HEART RATE ABNORMAL, SKIN DISCOLOURATION, BLOOD PRESSURE INCREASED	VISITED AN ER
146476^	12/7/11 3/27/12 4/4/12	MONSTER DRINKS	LOSS OF CONSCIOUSNESS	DEATH
146479	12/6/11	MONSTER ENERGY DRINK	HEART RATE IRREGULAR, DYSPNOEA, ATRIAL FIBRILLATION	HOSPITALIZATION
147297	12/30/11	MONSTER	DEATH	DEATH
147873	12/5/11	MONSTER ENERGY DRINK	ABDOMINAL PAIN	NON-SERIOUS INJURIES/ ILLNESS
150719	4/3/12	MONSTER ENERGY DRINK	FATIGUE, IRRITABILITY, DEPENDENCE	NON-SERIOUS INJURIES/ ILLNESS
150941	4/6/12	MONSTER	TREMOR, RESPIRATORY RATE INCREASED	VISITED A HEALTH CARE PROVIDER, HOSPITALIZATION
*150942^	3/27/12 4/9/12	MONSTER ENERGY DRINK	CARDIAC ARREST, ARRHYTHMIA, DRUG TOXICITY	DEATH
151016	4/9/12	MONSTER ENERGY DRINKS	DYSPNOEA, CHEST PAIN	VISITED AN ER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
151782	4/27/12	MONSTER ENERGY REHAB PROTEAN + ENERGY 15.5 OZ	THROAT TIGHTNESS, HYPERSENSITIVITY	HOSPITALIZATION
152471	5/15/12	MONSTER ENERGY	DIARRHOEA, VOMITING, CHROMATURIA, JAUNDICE, PRURITUS, ANOREXIA, BILIARY SPHINCTEROTOMY, CHOLESTASIS, GALLBLADDER DISORDER, PANCREATIC DISORDER	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), HOSPITALIZATION

Report #	Received Date	Brand/Product Name	Symptoms	Outcomes
153012	5/31/12	MONSTER ENERGY REHAB PROTEAN	RESPIRATORY ARREST, CARDIAC ARREST	HOSPITALIZATION
153279	6/11/12	MONSTER ENERGY 16 OZ	DIZZINESS, TREMOR, ANXIETY	HOSPITALIZATION
153974	6/29/12	MONSTER ENERGY IMPORT DUB EDITION	OROPHARYNGEAL SWELLING	VISITED AN ER, HOSPITALIZATION
154641	7/20/12	MONSTER ENERGY IMPORT	CONFUSIONAL STATE, CHEST PAIN, PAIN, HEADACHE, CHILLS, DIZZINESS	VISITED AN ER, HOSPITALIZATION
155221	8/7/12	MONSTER ENERGY 16 OZ	DYSPNOEA, FEELING JITTERY, HYPOAESTHESIA	HOSPITALIZATION
155267	8/8/12	MONSTER ENERGY	HYPERSENSITIVITY, EMOTIONAL DISTRESS, URTICARIA	VISITED AN ER, HOSPITALIZATION
155411	8/10/12	MONSTER ENERGY DRINK	HYPERSENSITIVITY, MALAISE	CONGENITAL ANOMALY, REQ. INTERVENTION TO PRVNT PERM. IMPRMNT., LIFE THREATENING, DISABILITY
155735	8/22/12	MONSTER ENERGY	HEART RATE INCREASED, PALPITATIONS, FALL	HOSPITALIZATION
155835	8/27/12	MONSTER ENERGY ANTI- GRAVITY 12 FL. OZ	ORAL HERPES, HYPERSENSITIVITY, RASH, PRURITUS	HOSPITALIZATION
156002	8/30/12	MONSTER ENERGY ABSOLUTELY ZERO	ABDOMINAL PAIN UPPER, VOMITING, SYNCOPE, DIARRHOEA, DEHYDRATION	HOSPITALIZATION
156830	9/20/12	MONSTER ENERGY	CHOKING, HAEMORRHAGE, FOREIGN BODY TRAUMA, RETCHING	VISITED AN ER, HOSPITALIZATION
157791	10/11/12	MONSTER ENERGY REHAB GREEN TEA 15.5OZ	SYNCOPE, MYOCARDIAL INFARCTION, FOOD POISONING, DIZZINESS, FEELING ABNORMAL	VISITED A HEALTH CARE PROVIDER
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CAERS Adverse Events Reports Allegedly Related to Rockstar

Search Terms: Rockstar, Rock Star

The Center for Food Safety Adverse Event Reporting System (CAERS) is a post-market surveillance system that collects reports about events or problems that are allegedly related to CFSAN regulated products. In some reports, information in the reports cannot be verified for accuracy. Furthermore, in many reports, individuals may have used other products, and many products contain multiple ingredients which further complicates the evaluation of adverse event reports.

There is no certainty that a reported adverse event can be attributed to a particular product or ingredient. The number of adverse event reports in CAERS received by FDA and the adverse event report itself about a particular product only reflects information **AS REPORTED** and does not represent any conclusion by FDA regarding a causal relationship or association with the product or ingredient. Due to the continuous inclusion of new or updated information into the CAERS system, reports released from CAERS containing adverse event data may change over time.

Each report received by CAERS regarding an individual that experiences an adverse event is assigned a unique report number (Report #).

^ Additional dates indicate receipt of additional materials on report.

Report #	Received Date	Brand/Product Name	Symptoms	Outcomes
83060	1/3/06	ROCKSTAR ENERGEY DRINK	NAUSEA	NON-SERIOUS INJURIES/ ILLNESS
86399	6/20/06	ROCKSTAR ENERGY FUEL	NAUSEA, HYPERHIDROSIS, HEART RATE INCREASED, OVERDOSE	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
87069	7/13/06	DIET ROCKSTAR ENERGY DRINK SOFT DRINK	INFLUENZA LIKE ILLNESS, ABDOMINAL DISTENSION, NAUSEA	NON-SERIOUS INJURIES/ ILLNESS
92129	3/19/07	DIET ROCK STAR	HYPERTENSION, BLOOD PRESSURE INCREASED, HEART RATE INCREASED, SUPRAVENTRICULAR TACHYCARDIA	DISABILITY, VISITED AN ER, HOSPITALIZATION
100226	2/8/08	ROCKSTAR ENERGY DRINK	NAUSEA, DIZZINESS, HEADACHE, HEART RATE INCREASED, LOSS OF CONSCIOUSNESS, TACHYCARDIA, IRRITABILITY	HOSPITALIZATION
111130	3/9/09	ROCKSTAR ZERO CARB ENERGY DRINK	VOMITING, CRYING, ANXIETY	VISITED A HEALTH CARE PROVIDER, VISITED AN ER
113062	5/7/09	ROCKSTAR ENERGY DRINK	MANIA, PSYCHOTIC DISORDER, INSOMNIA, BIPOLAR DISORDER	VISITED AN ER, HOSPITALIZATION

Report #	Received Date	Brand/Product Name	Symptoms	Outcomes
114915	7/1/09	ROCKSTAR ENERGY DRINK	ARTERIAL DISORDER, INFARCTION, CEREBROVASCULAR ACCIDENT, BIOPSY BLOOD VESSEL ABNORMAL	HOSPITALIZATION, DISABILITY
116889	7/13/09	ROCK STAR ROASTED COFFEE AND ENERGY MOCHA AND CREAM COFFEE	LACERATION, THROAT IRRITATION	VISITED AN ER, VISITED A HEALTH CARE PROVIDER
120455	5/19/08	ROCKSTAR JUICED ENERGY + GUAVA ENERGY DRINK	NAUSEA, DIARRHOEA, VOMITING, BURNING SENSATION	NON-SERIOUS INJURIES/ ILLNESS
127121	6/1/10	ROCKSTAR ENERGY DRINK AND POWER SHOT	HEART RATE ABNORMAL, VOMITING, NERVOUSNESS	VISITED AN ER
131960	9/24/10	ROCK STAR ENERGY DRINK	ABDOMINAL PAIN	NON-SERIOUS INJURIES/ ILLNESS
156595	9/13/12	ROCKSTAR INC ROCKSTAR ZERO CARB ZERO SUGAR	DYSGEUSIA	NON-SERIOUS INJURIES/ ILLNESS
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