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)
92				

FOI 15-1399
CAERS Reports Allegedly Related to 5-Hour Energy Products
Search Terms: Products Listed

FDA's Center for Food Safety and Applied Nutrition's (CFSAN's) Adverse Event Reporting System (CAERS) is a post-market surveillance system that collects reports about adverse events and product complaints that are allegedly related to CFSAN-regulated products. These products include conventional foods (and beverages), dietary supplements, infant formulas and cosmetics.

The adverse event reports about a 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. The attached reports are what have been **entered into CAERS during the requested dates** (the search date used was the CAERS entered date, as opposed to other dates such as the FDA Received Date or CAERS Received Date, etc.).

The reports submitted to FDA vary in the quality and reliability of the information provided. Some reports to FDA do not necessarily include all relevant data, such as whether an individual also suffered from other medical conditions or used other products or medications 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 a 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. There also 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.

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.

Report #	Received Date	Brand/Product Name	Symptoms	Outcomes
147296	12/30/11	5 HOUR ENERGY	HOSPITALISATION	HOSPITALIZATION
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 5 HOUR ENERGY POMEGRANATE	DYSPNOEA, TREMOR, HYPOAESTHESIA, CHEST PAIN	HOSPITALIZATION, VISITED AN ER, NON-SERIOUS INJURIES/ ILLNESS
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	5 HOUR ENERGY BERRY	MYOCARDIAL INFARCTION, CHEST PAIN	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), HOSPITALIZATION, VISITED AN ER, VISITED A HEALTH CARE PROVIDER
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 BERRY 5 HOUR ENERGY EXTRA STRENGTH GRAPE	FATIGUE, MIGRAINE, DIZZINESS, NAUSEA, AGITATION, DEPENDENCE, MALAISE, DRUG WITHDRAWAL SYNDROME, FEELING ABNORMAL	HOSPITALIZATION
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 POMEGRANATE	LOSS OF CONSCIOUSNESS, HEAD INJURY, DIZZINESS, CONCUSSION, TREMOR, CONVULSION, BRAIN OEDEMA	VISITED AN ER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
	8/31/12	5-HOUR ENERGY POMEGRANATE	LOSS OF CONSCIOUSNESS, HEAD INJURY, DIZZINESS, CONCUSSION, TREMOR, CONVULSION, BRAIN OEDEMA	VISITED AN ER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
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	5-HOUR ENERGY GRAPE	ERYTHEMA, PRURITUS, TONGUE OEDEMA, URTICARIA, OBSTRUCTIVE AIRWAYS DISORDER, DYSPHAGIA	VISITED AN ER, LIFE THREATENING
155222	8/7/12	5-HOUR ENERGY	COELIAC DISEASE	HOSPITALIZATION
155230	8/7/12	5 HOUR ENERGY	COMPLETED SUICIDE	DEATH
156247	8/30/12	FIVE HOUR ENERGY EXTRA STRENGTH/ BERRY FLAVOR CAFFEINE ENERGY BOOSTER		NONE
156365	9/10/12	5 HOUR ENERGY	HOSPITALISATION	HOSPITALIZATION
	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
	10/31/12	5 HOUR ENERGY	SUDDEN CARDIAC DEATH, FATIGUE, LOSS OF CONSCIOUSNESS, MYOCARDIAL INFARCTION	DEATH

Report #	Received Date	Brand/Product Name	Symptoms	Outcomes
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)
158326	10/30/12	5-HOUR ENERGY	TRANSIENT ISCHAEMIC ATTACK, VITAMIN B12 INCREASED	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
158329	10/31/12	5-HOUR ENERGY	HEART INJURY	DEATH
158481	11/1/12	EXTRA STENGTH FIVE HOUR ENERGY FOUR OUNCE BOTTLE	HEART RATE IRREGULAR	HOSPITALIZATION
159146	11/20/12	5-HOUR ENERGY	CONVULSION	VISITED AN ER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
	12/27/12	5-HOUR ENERGY	CONVULSION	VISITED AN ER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
159195	11/21/12	5-HOUR ENERGY EXTRA STRENGTH BERRY	HYPERHIDROSIS, NAUSEA, HEART RATE IRREGULAR, HEART RATE INCREASED, CHEST PAIN	VISITED AN ER, HOSPITALIZATION
159196	11/21/12	5-HOUR ENERGY	DEATH	DEATH
159197	11/21/12	5-HOUR ENERGY EXTRA STRENGTH GRAPE	PALPITATIONS, ATRIAL FIBRILLATION, HEART RATE INCREASED	HOSPITALIZATION, VISITED AN ER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
159315	11/23/12	5-HOUR ENERGY LIVING ESSENTIALS DRINK	MYOCARDIAL INFARCTION, OBESITY, CARDIAC FAILURE CONGESTIVE, HYPERTENSION, BLOOD GLUCOSE DECREASED, BLOOD CHOLESTEROL INCREASED, RED CELL DISTRIBUTION WIDTH DECREASED, HAEMOGLOBIN INCREASED, WHITE BLOOD CELL COUNT INCREASED, HAEMATOCRIT INCREASED, LOW DENSITY LIPOPROTEIN INCREASED, CARBON DIOXIDE INCREASED	DEATH
	11/27/12	5-HOUR ENERGY LIVING ESSENTIALS DRINK	MYOCARDIAL INFARCTION, OBESITY, CARDIAC FAILURE CONGESTIVE, HYPERTENSION, BLOOD GLUCOSE DECREASED, BLOOD CHOLESTEROL INCREASED, RED CELL DISTRIBUTION WIDTH DECREASED, HAEMOGLOBIN INCREASED, WHITE BLOOD CELL COUNT INCREASED, HAEMATOCRIT INCREASED, LOW DENSITY LIPOPROTEIN INCREASED, CARBON DIOXIDE INCREASED	DEATH
159323	11/23/12	FIVE HOUR ENERGY REGULAR STRENGTH	URTICARIA, DYSPNOEA, VOMITING, ANAPHYLACTIC SHOCK, PANIC REACTION	LIFE THREATENING

Report #	Received Date	Brand/Product Name	Symptoms	Outcomes
159324	11/23/12	5 HOUR ENERGY	BACK PAIN, ACTIVITIES OF DAILY LIVING IMPAIRED, ABDOMINAL PAIN UPPER, GASTROENTERITIS, CARDIAC DISORDER, ENDOSCOPY ABNORMAL, CHEST DISCOMFORT	VISITED A HEALTH CARE PROVIDER, DISABILITY
159325	11/23/12	FIVE HOUR ENERGY	BLOOD PRESSURE INCREASED	VISITED AN ER, HOSPITALIZATION
159326	11/23/12	5 HOUR ENERGY	CONVULSION	HOSPITALIZATION, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
	12/27/12	5 HOUR ENERGY	CONVULSION	HOSPITALIZATION, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
159327	11/23/12	5 HOUR ENERGY	MYOCARDIAL INFARCTION, THROMBOSIS, CORONARY ARTERY OCCLUSION	HOSPITALIZATION, DISABILITY, LIFE THREATENING
	12/27/12	5 HOUR ENERGY	MYOCARDIAL INFARCTION, THROMBOSIS, CORONARY ARTERY OCCLUSION	HOSPITALIZATION, DISABILITY, LIFE THREATENING
159420	11/28/12	5 HOUR ENERGY DRINK	TREMOR, CONVULSION, HYPERHIDROSIS, HEART RATE INCREASED, ELECTROCARDIOGRAM ABNORMAL, BLOOD PRESSURE ABNORMAL	VISITED AN ER, HOSPITALIZATION
159464	11/27/12	5 HOUR ENERGY	MYOCARDIAL INFARCTION, CORONARY ARTERY OCCLUSION, TORSADE DE POINTES, HEART RATE DECREASED, ARTERIOSCLEROSIS CORONARY ARTERY, ANGINA PECTORIS, CORONARY ARTERY DISEASE, ARRHYTHMIA	HOSPITALIZATION, LIFE THREATENING, VISITED AN ER, REQ. INTERVENTION TO PRVNT PERM. IMPRMNT., OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
	12/27/12	5 HOUR ENERGY	MYOCARDIAL INFARCTION, CORONARY ARTERY OCCLUSION, TORSADE DE POINTES, HEART RATE DECREASED, ARTERIOSCLEROSIS CORONARY ARTERY, ANGINA PECTORIS, CORONARY ARTERY DISEASE, ARRHYTHMIA	HOSPITALIZATION, LIFE THREATENING, VISITED AN ER, REQ. INTERVENTION TO PRVNT PERM. IMPRMNT., OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
159492	11/27/12	5 HOUR ENERGY	HAEMORRHAGIC STROKE	HOSPITALIZATION, VISITED AN ER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), LIFE THREATENING
	1/11/13	5 HOUR ENERGY	HAEMORRHAGIC STROKE	HOSPITALIZATION, VISITED AN ER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), LIFE THREATENING
	1/22/13	5 HOUR ENERGY	HAEMORRHAGIC STROKE	HOSPITALIZATION, VISITED AN ER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), LIFE THREATENING
159552	11/19/12	FIVE HOUR ENERGY BOOSTER	DIARRHOEA, VOMITING, CHROMATURIA, JAUNDICE, PRURITUS, ABDOMINAL PAIN, MALAISE, PANCREATIC DISORDER, CHOLESTASIS, BLOOD BILIRUBIN INCREASED, BILE DUCT STENOSIS, ANOREXIA, LIVER INJURY, GALLBLADDER DISORDER, ALANINE AMINOTRANSFERASE INCREASED, ASPARTATE AMINOTRANSFERASE INCREASED, NAUSEA	HOSPITALIZATION
159705	12/3/12	5-HOUR ENERGY BERRY 5-HOUR ENERGY GRAPE	OESOPHAGEAL RUPTURE, BURNING SENSATION, DYSPEPSIA, DYSPNOEA	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
159706	12/3/12	5-HOUR ENERGY	TRANSIENT ISCHAEMIC ATTACK, MOTOR DYSFUNCTION, RESTLESS LEGS SYNDROME, VITAMIN B12 INCREASED, MUSCULAR WEAKNESS	VISITED A HEALTH CARE PROVIDER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
159795	12/7/12	5-HOUR ENERGY BERRY	URTICARIA, HYPERSENSITIVITY, DYSPNOEA, OROPHARYNGEAL SWELLING	LIFE THREATENING, VISITED AN ER, SERIOUS INJURIES/ ILLNESS
159796	12/7/12	5-HOUR ENERGY	LOSS OF CONSCIOUSNESS, ARRHYTHMIA	HOSPITALIZATION

Report #	Received Date	Brand/Product Name	Symptoms	Outcomes
159797	12/7/12	5-HOUR ENERGY	MYOCARDIAL INFARCTION	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
159798	12/7/12	5-HOUR ENERGY POMEGRANATE	CONVULSION, MEAN CELL HAEMOGLOBIN DECREASED, MEAN CELL VOLUME DECREASED, WHITE BLOOD CELL COUNT INCREASED, BLOOD SODIUM DECREASED, CARBON DIOXIDE DECREASED, MONOCYTE COUNT INCREASED, LYMPHOCYTE COUNT DECREASED, BLOOD GLUCOSE INCREASED, GRANULOCYTE COUNT INCREASED, RED CELL DISTRIBUTION WIDTH INCREASED	VISITED AN ER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
	3/14/13	5-HOUR ENERGY POMEGRANATE	CONVULSION, MEAN CELL HAEMOGLOBIN DECREASED, MEAN CELL VOLUME DECREASED, WHITE BLOOD CELL COUNT INCREASED, BLOOD SODIUM DECREASED, CARBON DIOXIDE DECREASED, MONOCYTE COUNT INCREASED, LYMPHOCYTE COUNT DECREASED, BLOOD GLUCOSE INCREASED, GRANULOCYTE COUNT INCREASED, RED CELL DISTRIBUTION WIDTH INCREASED	VISITED AN ER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
	5/24/13	5-HOUR ENERGY POMEGRANATE	CONVULSION, MEAN CELL HAEMOGLOBIN DECREASED, MEAN CELL VOLUME DECREASED, WHITE BLOOD CELL COUNT INCREASED, BLOOD SODIUM DECREASED, CARBON DIOXIDE DECREASED, MONOCYTE COUNT INCREASED, LYMPHOCYTE COUNT DECREASED, BLOOD GLUCOSE INCREASED, GRANULOCYTE COUNT INCREASED, RED CELL DISTRIBUTION WIDTH INCREASED	VISITED AN ER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
159799	12/7/12	5-HOUR ENERGY	CHEST PAIN, NAUSEA, MASS	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
159800	12/7/12	5-HOUR ENERGY	PANCREATITIS	SERIOUS INJURIES/ ILLNESS, HOSPITALIZATION
159875	12/7/12	5-HOUR ENERGY POMEGRANATE	BLOOD PRESSURE INCREASED, HEART RATE INCREASED	HOSPITALIZATION
160030	12/12/12	5-HOUR ENERGY EXTRA STRENGTH BERRY 5-HOUR ENERGY EXTRA STRENGTH GRAPE	CONVULSION	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), VISITED AN ER
160031	12/12/12	5-HOUR ENERGY BERRY	DEATH, MYOCARDIAL INFARCTION	DEATH
160032	12/12/12	5-HOUR ENERGY	ANAPHYLACTIC SHOCK	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
160033	12/12/12	5-HOUR ENERGY	HOSPITALISATION	HOSPITALIZATION

Report #	Received Date	Brand/Product Name	Symptoms	Outcomes
160034	12/12/12	5-HOUR ENERGY	HYPOAESTHESIA, BLOOD PRESSURE INCREASED, PARAESTHESIA, VITAMIN B12 INCREASED, ANTINUCLEAR ANTIBODY INCREASED, ANTINUCLEAR ANTIBODY POSITIVE, MIGRAINE, CLUSTER HEADACHE	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), HOSPITALIZATION
	12/27/12	5-HOUR ENERGY	HYPOAESTHESIA, BLOOD PRESSURE INCREASED, PARAESTHESIA, VITAMIN B12 INCREASED, ANTINUCLEAR ANTIBODY INCREASED, ANTINUCLEAR ANTIBODY POSITIVE, MIGRAINE, CLUSTER HEADACHE	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), HOSPITALIZATION
	3/22/13	5-HOUR ENERGY	HYPOAESTHESIA, BLOOD PRESSURE INCREASED, PARAESTHESIA, VITAMIN B12 INCREASED, ANTINUCLEAR ANTIBODY INCREASED, ANTINUCLEAR ANTIBODY POSITIVE, MIGRAINE, CLUSTER HEADACHE	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), HOSPITALIZATION
160556	12/27/12	5-HOUR ENERGY	DEATH	DEATH
160922	1/8/13	5 HOUR ENERGY	DIZZINESS, VERTIGO, AUTONOMIC NERVOUS SYSTEM IMBALANCE, MALAISE, VOMITING, INNER EAR DISORDER, FEELING ABNORMAL, TREMOR, VERTIGO POSITIONAL, HYPERSENSITIVITY, MENTAL IMPAIRMENT, HYPERHIDROSIS	HOSPITALIZATION, VISITED AN ER, VISITED A HEALTH CARE PROVIDER
161401	1/3/13	ORGINAL 5-HOUR ENERGY DRINK	FEELING OF BODY TEMPERATURE CHANGE, HEART RATE ABNORMAL, SKIN DISCOLOURATION, PARAESTHESIA, ERYTHEMA, COLD SWEAT, HEART RATE INCREASED	VISITED AN ER
161688	12/10/12	5-HOUR ENERGY LEMON LIME		NONE
162045	11/16/12	5 HOUR ENERGY DRINK	CARDIOVASCULAR DISORDER, PAIN, MYOCARDIAL INFARCTION	VISITED A HEALTH CARE PROVIDER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), HOSPITALIZATION, VISITED AN ER
	3/1/13	5 HOUR ENERGY DRINK	CARDIOVASCULAR DISORDER, PAIN, MYOCARDIAL INFARCTION	VISITED A HEALTH CARE PROVIDER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), HOSPITALIZATION, VISITED AN ER
162048	11/28/12	5 HOUR ENERGY	LOSS OF CONSCIOUSNESS, FALL, HEAD INJURY, DEHYDRATION, SUBARACHNOID HAEMORRHAGE, POST CONCUSSION SYNDROME, CONVULSION, SYNCOPE	HOSPITALIZATION, DISABILITY, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), VISITED AN ER
	3/1/13	5 HOUR ENERGY	LOSS OF CONSCIOUSNESS, FALL, HEAD INJURY, DEHYDRATION, SUBARACHNOID HAEMORRHAGE, POST CONCUSSION SYNDROME, CONVULSION, SYNCOPE	HOSPITALIZATION, DISABILITY, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), VISITED AN ER
162637	2/22/13	5-HOUR ENERGY	CARDIAC DISORDER	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
162638	2/22/13	5-HOUR ENERGY	CARDIAC DISORDER	VISITED A HEALTH CARE PROVIDER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
162975	3/4/13	5 HOUR ENERGY DRINK		HOSPITALIZATION
163354	3/14/13	5-HOUR ENERGY BERRY FLAVOR	FALL, MULTIPLE INJURIES, DEHYDRATION, DISABILITY, LOSS OF CONSCIOUSNESS, BRAIN INJURY	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), DISABILITY

Report #	Received Date	Brand/Product Name	Symptoms	Outcomes
163355	3/14/13	5-HOUR ENERGY (BERRY)	NAUSEA, CEREBROVASCULAR ACCIDENT, DIZZINESS	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), HOSPITALIZATION
163657	3/22/13	5-HOUR ENERGY	MYOCARDIAL INFARCTION	DEATH
163729	3/22/13	5-HOUR ENERGY	MANIA, INSOMNIA, DEPRESSED MOOD, SUICIDAL IDEATION, MEMORY IMPAIRMENT, ANXIETY, HAEMORRHAGE, PSYCHOTIC DISORDER	DEATH, VISITED AN ER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), HOSPITALIZATION
	5/6/13	5-HOUR ENERGY	MANIA, INSOMNIA, DEPRESSED MOOD, SUICIDAL IDEATION, MEMORY IMPAIRMENT, ANXIETY, HAEMORRHAGE, PSYCHOTIC DISORDER	DEATH, VISITED AN ER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), HOSPITALIZATION
163731	3/22/13	5-HOUR ENERGY EXTRA STRENGTH BERRY	CONVULSION, FOAMING AT MOUTH, GRAND MAL CONVULSION, ELECTROENCEPHALOGRAM ABNORMAL, MYOCLONIC EPILEPSY	VISITED A HEALTH CARE PROVIDER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
	5/15/13	5-HOUR ENERGY EXTRA STRENGTH BERRY	CONVULSION, FOAMING AT MOUTH, GRAND MAL CONVULSION, ELECTROENCEPHALOGRAM ABNORMAL, MYOCLONIC EPILEPSY	VISITED A HEALTH CARE PROVIDER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
163852	3/28/13	5-HOUR ENERGY BERRY	MYOCARDIAL INFARCTION	HOSPITALIZATION, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
163854	3/28/13	5-HOUR ENERGY BERRY	PALPITATIONS, ATRIAL FIBRILLATION, DYSPNOEA	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), VISITED AN ER, VISITED A HEALTH CARE PROVIDER, HOSPITALIZATION
	5/24/13	5-HOUR ENERGY BERRY	PALPITATIONS, ATRIAL FIBRILLATION, DYSPNOEA	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), VISITED AN ER, VISITED A HEALTH CARE PROVIDER, HOSPITALIZATION
163905	3/29/13	5 HOUR ENERGY	PALPITATIONS	VISITED A HEALTH CARE PROVIDER
164311	4/9/13	5-HOUR ENERGY DRINK	CHEST PAIN, HEADACHE, DYSPNOEA, WHEEZING, INSOMNIA, FATIGUE, WEIGHT INCREASED, OEDEMA, MUSCLE SPASMS	HOSPITALIZATION, LIFE THREATENING
165549	5/15/13	5-HOUR ENERGY	VOMITING, CHOKING, ASPIRATION	DEATH
167339	6/28/13	5 HOUR ENERGY BERRY LIVING ESSENTIALS, LLC	CEREBROVASCULAR ACCIDENT	DISABILITY, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), LIFE THREATENING, HOSPITALIZATION
167351	6/28/13	5-HOUR ENERGY	DIZZINESS, MALAISE	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), HOSPITALIZATION
167846	7/10/13	5-HOUR ENERGY	MYOCARDIAL INFARCTION	DEATH
168025	7/18/13	5-HOUR ENERGY ORANGE	NAUSEA, DEPRESSED MOOD	HOSPITALIZATION, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
168029	7/18/13	5-HOUR ENERGY ORANGE	NAUSEA, DEPRESSED MOOD	HOSPITALIZATION

Report #	Received Date	Brand/Product Name	Symptoms	Outcomes
168390	4/5/13	5-HOUR ENERGY	CHEST PAIN, URINE ANALYSIS ABNORMAL, HEADACHE, ABNORMAL LOSS OF WEIGHT, APPETITE DISORDER, SYNCOPE, LETHARGY, OEDEMA, SWELLING, GAIT DISTURBANCE, BLISTER, SLEEP DISORDER, MUSCLE SPASMS, PAIN, FATIGUE, DYSPNOEA, RASH PAPULAR, CIRCULATORY COLLAPSE	LIFE THREATENING, HOSPITALIZATION, VISITED A HEALTH CARE PROVIDER, VISITED AN ER, REQ. INTERVENTION TO PRVNT PERM. IMPRMNT.
169203	8/16/13	5 HOUR ENERGY	NAUSEA, PALPITATIONS, VOMITING	VISITED AN ER
170296	9/18/13	5-HOUR ENERGY EXTRA STRENGTH BERRY	DYSARTHRIA, CEREBROVASCULAR ACCIDENT, HYPERTENSION, AMNESIA	DISABILITY, VISITED AN ER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), HOSPITALIZATION
170297	9/18/13	5-HOUR ENERGY PINK LEMONADE	LOSS OF CONSCIOUSNESS, DYSPHAGIA, CONVULSION, DISORIENTATION, CONFUSIONAL STATE, EXOPHTHALMOS, ANOREXIA	VISITED AN ER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
170967	10/16/13	5 HOUR ENERGY DRINK	CONVULSION	LIFE THREATENING, HOSPITALIZATION
170969	10/2/13	5-HOUR ENERGY EXTRA STRENGTH BERRY	CONVULSION, LOSS OF CONSCIOUSNESS, LOSS OF CONSCIOUSNESS, VOMITING, FOAMING AT MOUTH, MUSCULOSKELETAL STIFFNESS, TENDERNESS, DIZZINESS, SKIN LACERATION, PERFORMANCE STATUS DECREASED	LIFE THREATENING, HOSPITALIZATION
170975	10/2/13	5-HOUR ENERGY BERRY	LOSS OF CONSCIOUSNESS, CONVULSION, FOAMING AT MOUTH, ABDOMINAL PAIN UPPER, MUSCLE SPASMS	VISITED A HEALTH CARE PROVIDER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
170977	10/2/13	5-HOUR ENERGY	COLECTOMY	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
171094	10/23/13	5 HOUR ENERGY DRINK	FEELING DRUNK	VISITED A HEALTH CARE PROVIDER
171143	10/15/13	5-HOUR ENERGY	CONVULSION, OVERDOSE	HOSPITALIZATION, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
171218	10/18/13	5-HOUR ENERGY	MYOCARDIAL INFARCTION	DISABILITY, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), HOSPITALIZATION
171333	10/21/13	5 HOUR ENERGY DRINK	SOMNOLENCE, VISUAL IMPAIRMENT, PARALYSIS, DYSGRAPHIA, DYSPHEMIA, CEREBROVASCULAR ACCIDENT	LIFE THREATENING, HOSPITALIZATION
172173	6/25/13	5-HOUR ENERGY ORANGE FLAVORED LIQUID DIETARY SUPPLEMENT	VOMITING, HEART RATE ABNORMAL, LETHARGY, LOSS OF CONSCIOUSNESS, MALAISE, BRADYCARDIA, MENTAL STATUS CHANGES, MUSCLE SPASMS	HOSPITALIZATION, VISITED AN ER, REQ. INTERVENTION TO PRVNT PERM. IMPRMNT.
172193	11/14/13	5-HOUR ENERGY (BERRY)	HOSPITALISATION	HOSPITALIZATION
172194	11/14/13	5-HOUR ENERGY (BERRY)	SOMNAMBULISM	HOSPITALIZATION

Report #	Received Date	Brand/Product Name	Symptoms	Outcomes
172238	11/22/13	5-HOUR ENERGY BERRY	LOSS OF CONSCIOUSNESS, MIGRAINE WITH AURA, SOMNOLENCE, SCAR	HOSPITALIZATION, DISABILITY
172392	11/14/13	5-HOUR ENERGY	BLOOD TEST ABNORMAL, ORGAN FAILURE, NERVE INJURY, DACRYOSTENOSIS CONGENITAL	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
172538	6/25/13	5-HOUR ENERGY ORANGE FLAVORED LIQUID DIETARY SUPPLEMENT	BRADYCARDIA, MUSCLE SPASMS, MALAISE, LOSS OF CONSCIOUSNESS, VOMITING, MENTAL STATUS CHANGES, HEART RATE ABNORMAL, LETHARGY	HOSPITALIZATION, VISITED AN ER, REQ. INTERVENTION TO PRVNT PERM. IMPRMNT.
173345	12/27/13	5-HOUR ENERGY	CONVULSION	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
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FOI 15-1828
CAERS Reports Allegedly Related 5-Hour Energy Products
Search Terms: Products Listed

FDA's Center for Food Safety and Applied Nutrition's (CFSAN's) Adverse Event Reporting System (CAERS) is a post-market surveillance system that collects reports about adverse events and product complaints that are allegedly related to CFSAN-regulated products. These products include conventional foods (and beverages), dietary supplements, infant formulas and cosmetics.

The adverse event reports about a 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. The attached reports are what have been **entered into CAERS during the requested dates** (the search date used was the CAERS entered date, as opposed to other dates such as the FDA Received Date or CAERS Received Date, etc.).

The reports submitted to FDA vary in the quality and reliability of the information provided. Some reports to FDA do not necessarily include all relevant data, such as whether an individual also suffered from other medical conditions or used other products or medications 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 a 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. There also 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.

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.

Report #	Received Date	Brand/Product Name	Symptoms	Outcomes
174340	2/28/14	5-HOUR ENERGY EXTRA STRENGTH	PARAESTHESIA, HYPERSENSITIVITY, ERYTHEMA, THROAT TIGHTNESS, THROAT TIGHTNESS	VISITED AN ER, LIFE THREATENING
174762	3/11/14	5 HOUR ENERGY POMEGRANATE	LOSS OF CONSCIOUSNESS, CONVULSION	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), HOSPITALIZATION
174763	3/11/14	5 HOUR ENERGY	ATRIAL FIBRILLATION	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
174881	11/20/13	5 HOUR ENERGY SHOT		NONE
175076	3/28/14	EXTRA STRENGHT 5-HOUR ENERGY GRAPE EXTRA STRENGTH 5-HOUR ENERGY SOUR APPLE	JAUNDICE, LIVER FUNCTION TEST ABNORMAL, ABDOMINAL PAIN UPPER, VOMITING, GALLBLADDER DISORDER, PAIN	VISITED AN ER, HOSPITALIZATION
175855	4/16/14	5 HOUR ENERGY	HEADACHE, PAIN, NAUSEA, CHEST PAIN, HEART RATE INCREASED, HEART RATE IRREGULAR, HYPERHIDROSIS	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), HOSPITALIZATION
	5/8/14	5 HOUR ENERGY	HEADACHE, PAIN, NAUSEA, CHEST PAIN, HEART RATE INCREASED, HEART RATE IRREGULAR, HYPERHIDROSIS	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), HOSPITALIZATION
175856	4/16/14	5 HOUR ENERGY ORANGE	TRANSIENT ISCHAEMIC ATTACK, DIZZINESS, DIZZINESS	HOSPITALIZATION, VISITED AN ER, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
177372	6/24/14	5 - HOUR ENERGY	CHEST PAIN, CARDIAC ARREST, LOSS OF CONSCIOUSNESS, ARRHYTHMIA	DEATH, HOSPITALIZATION
	7/24/14	5 - HOUR ENERGY	CHEST PAIN, CARDIAC ARREST, LOSS OF CONSCIOUSNESS, ARRHYTHMIA	DEATH, HOSPITALIZATION

Report #	Received Date	Brand/Product Name	Symptoms	Outcomes
177400	1/6/14	5-HOUR ENERGY	PALPITATIONS, MYOCARDIAL INFARCTION	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
177730	7/7/14	5-HOUR ENERGY	REVERSIBLE POSTERIOR LEUKOENCEPHALOPATHY SYNDROME	HOSPITALIZATION, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), LIFE THREATENING
177785	7/9/14	5-HOUR ENERGY (LIVING ESSENTIALS) ()	HYPERTENSION, CARDIOMEGALY, HEPATIC STEATOSIS, DRUG TOXICITY	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), DEATH
178475	8/6/14	5 HOUR ENERGY	SJOGREN'S SYNDROME, VASCULITIS, HAEMORRHAGE	DISABILITY, OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
178644	8/14/14	5-HOUR ENERGY BERRY 5-HOUR ENERGY EXTRA STRENGTH BERRY	LETHARGY, DEHYDRATION, DIARRHOEA, ABDOMINAL PAIN UPPER, VOMITING, STAPHYLOCOCCAL INFECTION, PRE-EXISTING CONDITION IMPROVED, BLOOD POTASSIUM DECREASED, INFLAMMATION	VISITED AN ER, HOSPITALIZATION
179114	9/4/14	5-HOUR ENERGY	MYOCARDIAL INFARCTION	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
179710	10/1/14	LIVING ESSENTIALS 5 HOUR ENERGY EXTRA STRENGTH	COMA, DISSEMINATED INTRAVASCULAR COAGULATION, METABOLIC ACIDOSIS, RENAL FAILURE, RHABDOMYOLYSIS, ACUTE HEPATIC FAILURE, ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED, BLOOD BILIRUBIN INCREASED, BLOOD CREATINE PHOSPHOKINASE INCREASED, ASPARTATE AMINOTRANSFERASE INCREASED, PROTHROMBIN LEVEL INCREASED, ARRHYTHMIA, LOSS OF CONSCIOUSNESS, BODY TEMPERATURE DECREASED, ALANINE AMINOTRANSFERASE INCREASED	VISITED A HEALTH CARE PROVIDER, LIFE THREATENING
179961	10/8/14	LIVING ESSENTIALS 5-HOUR ENERGY	ANGINA PECTORIS, CHEST PAIN	VISITED AN ER, HOSPITALIZATION
	12/23/14	LIVING ESSENTIALS 5-HOUR ENERGY	ANGINA PECTORIS, CHEST PAIN	VISITED AN ER, HOSPITALIZATION
180334	10/24/14	LIVING ESSENTIALS 5-HOUR ENERGY ORIGINAL	CONVULSION, TROPONIN INCREASED, BLOOD CREATINE PHOSPHOKINASE INCREASED, HEPATIC ENZYME INCREASED, AGITATION, BLOOD PRESSURE INCREASED, MUSCLE CONTRACTIONS INVOLUNTARY, HEART RATE INCREASED, ANION GAP INCREASED, BLOOD LACTATE DEHYDROGENASE INCREASED, MYOGLOBIN BLOOD INCREASED, ASPARTATE AMINOTRANSFERASE INCREASED	HOSPITALIZATION, VISITED AN ER, REQ. INTERVENTION TO PRVNT PERM. IMPRMNT.
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