

FOI 14-17

CAERS Reports Allegedly Related to Multiple Energy Drinks

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 **5 G F 9 D C F H 9 8** and do not represent any conclusion by FDA about whether the product actually caused the adverse events. The attached reports are what have been **Y b h Y f Y X] b l c ' 7 5 9 F G ' X i f] b [' H Y f Y e i Y g h X ' X U H g "**

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. **R 5 X X] h c b U ' X U H g] b X] W U h Y f Y W] d h c Z U X X] h c b U ' a U H f] U g ' c b ' f Y d c f H "**

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 #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
111857	4/7/09	MONSTER ENERGY DRINK	DEATH	DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
121679	12/17/09	5 HOUR ENERGY	SNEEZING, FALL, VOMITING, CHEST PAIN, PULSE ABSENT, HEAD INJURY	VISITED A HEALTH CARE PROVIDER, DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
121679	12/30/09^	5 HOUR ENERGY	SNEEZING, FALL, VOMITING, CHEST PAIN, PULSE ABSENT, HEAD INJURY	VISITED A HEALTH CARE PROVIDER, DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
121679	3/1/10^	5 HOUR ENERGY	SNEEZING, FALL, VOMITING, CHEST PAIN, PULSE ABSENT, HEAD INJURY	VISITED A HEALTH CARE PROVIDER, DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
121680	12/17/09	5 HOUR ENERGY	DEATH	DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
121680	8/3/10^	5 HOUR ENERGY	DEATH	DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
129061	8/13/10	5 HOUR ENERGY 5 HOUR ENERGY	VENTRICULAR ARRHYTHMIA, LOSS OF CONSCIOUSNESS, PNEUMONIA, CONVULSION, ACUTE RESPIRATORY FAILURE, ANOXIC ENCEPHALOPATHY	HOSPITALIZATION, DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
129372	8/26/10	5 HOUR ENERGY	DEATH	DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
131692	10/28/10	5 HOUR ENERGY	SOMNOLENCE	DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
132041	11/12/10	MONSTER NITROUS	ISCHAEMIC CARDIOMYOPATHY, ARRHYTHMIA	DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
132041	6/21/12^	MONSTER NITROUS	ISCHAEMIC CARDIOMYOPATHY, ARRHYTHMIA	DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
132041	2/13/13^	MONSTER NITROUS	ISCHAEMIC CARDIOMYOPATHY, ARRHYTHMIA	DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
137118	3/24/11	5 HOUR ENERGY	MYOCARDIAL INFARCTION, DEATH	DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
139012	5/13/11	5 HOUR ENERGY	DEATH	DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
139013	5/13/11	5 HOUR ENERGY	DEATH	DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
142160	7/25/11	5 HOUR ENERGY	DEATH	DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
144858	10/24/11	5 HOUR ENERGY	MYOCARDIAL INFARCTION	DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
146476	12/7/11	MONSTER DRINKS	LOSS OF CONSCIOUSNESS	DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
146476	3/27/12^	MONSTER DRINKS	LOSS OF CONSCIOUSNESS	DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
146476	4/4/12^	MONSTER DRINKS	LOSS OF CONSCIOUSNESS	DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
147297	12/30/11	5-HOUR ENERGY	DEATH	DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
147297	12/30/11	MONSTER	DEATH	DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
150942	3/27/12	MONSTER ENERGY DRINK	CARDIAC ARREST, ARRHYTHMIA, DRUG TOXICITY, COMA, CEREBRAL ISCHAEMIA	DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
150942	4/9/12^	MONSTER ENERGY DRINK	CARDIAC ARREST, ARRHYTHMIA, DRUG TOXICITY, COMA, CEREBRAL ISCHAEMIA	DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
150942	6/28/12^	MONSTER ENERGY DRINK	CARDIAC ARREST, ARRHYTHMIA, DRUG TOXICITY, COMA, CEREBRAL ISCHAEMIA	DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
150942	10/25/12^	MONSTER ENERGY DRINK	CARDIAC ARREST, ARRHYTHMIA, DRUG TOXICITY, COMA, CEREBRAL ISCHAEMIA	DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
155230	8/7/12	5 HOUR ENERGY	COMPLETED SUICIDE	DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
157207	10/1/12	5 HOUR ENERGY	SUDDEN CARDIAC DEATH, FATIGUE, LOSS OF CONSCIOUSNESS, MYOCARDIAL INFARCTION	DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
157207	10/31/12^	5 HOUR ENERGY	SUDDEN CARDIAC DEATH, FATIGUE, LOSS OF CONSCIOUSNESS, MYOCARDIAL INFARCTION	DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
158329	10/31/12	5-HOUR ENERGY	HEART INJURY	DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
159196	11/21/12	5-HOUR ENERGY	DEATH	DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
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

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
159315	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

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
159494	11/27/12	MONSTER ENERGY DRINK	CARDIOMEGALY	DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
159748	12/5/12	MONSTER ENERGY DRINK (GREEN LABEL)	CARDIAC ARREST	DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
160031	12/12/12	5-HOUR ENERGY BERRY	DEATH, MYOCARDIAL INFARCTION	DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
160556	12/27/12	5-HOUR ENERGY	DEATH	DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
160712	1/2/13	MONSTER DRINK	ANXIETY, DYSPNOEA, MYOCARDIAL INFARCTION	DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
163657	3/22/13	5-HOUR ENERGY	MYOCARDIAL INFARCTION	DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
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

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
163729	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

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
165549	5/15/13	5-HOUR ENERGY	VOMITING, CHOKING, ASPIRATION	DEATH

Report #	CAERS Entered Date	Brand/Product Name	Symptoms	Outcomes
167846	7/10/13	5-HOUR ENERGY	MYOCARDIAL INFARCTION	DEATH
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