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 Reports on Red Bull 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 label Red Bull between January 1, 2004 and October 23, 2012. These products are currently marketed as conventional foods.

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.

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 has consumed a product does not necessarily mean that product caused the adverse event.

CAERS Adverse Events Reports Allegedly Related to Red Bull

Search Terms: Red Bull, Redbull

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
66175	1/29/04	REDBULL	ADVERSE DRUG REACTION, PANCREATITIS	HOSPITALIZATION
75388	1/10/05	RED BULL HIGH ENERGY DRINK	FATIGUE	VISITED A HEALTH CARE PROVIDER
81804	11/4/05	RED BULL	PANIC ATTACK, ANXIETY, VISION BLURRED, DIZZINESS, DECREASED APPETITE, FATIGUE, ADRENAL INSUFFICIENCY, INSOMNIA, CONFUSIONAL STATE, DISTURBANCE IN ATTENTION, PHYSICAL EXAMINATION, DEPENDENCE	VISITED A HEALTH CARE PROVIDER
86399	6/20/06	RED BULL ENERGY DRINK	NAUSEA, HYPERHIDROSIS, HEART RATE INCREASED, OVERDOSE	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
94048	6/22/07	RED BULL	CHEST PAIN, DYSPNOEA, DIZZINESS, BLOOD PRESSURE INCREASED, HEART RATE INCREASED	VISITED AN ER, LIFE THREATENING
95452	8/10/07	RED BULL	ACUTE MYOCARDIAL INFARCTION, INTRACARDIAC THROMBUS	VISITED A HEALTH CARE PROVIDER, LIFE THREATENING

Report #	Received Date	Brand/Product Name	Symptoms	Outcomes
99268	12/31/07	SUGAR FREE RED BULL	VISION BLURRED, NECK PAIN, PANIC ATTACK, ELECTROCARDIOGRAM, HEART RATE IRREGULAR, ANXIETY, DEPRESSED LEVEL OF CONSCIOUSNESS, SENSORY LOSS	NON-SERIOUS INJURIES/ ILLNESS, HOSPITALIZATION, VISITED A HEALTH CARE PROVIDER
100113	2/1/08	RED BULL	FLUSHING, TREMOR, TACHYCARDIA, LIVEDO RETICULARIS	VISITED AN ER, HOSPITALIZATION
100976	3/3/08	RED BULL DRINK	VERTIGO, BLINDNESS, VOMITING, NAUSEA	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
115086	3/2/08	RED BULL DRINK	CHEST PAIN, BLOOD PRESSURE FLUCTUATION, DIARRHOEA, ABDOMINAL PAIN, FAECES DISCOLOURED, GLOSSODYNIA, HYPERSENSITIVITY	VISITED A HEALTH CARE PROVIDER, VISITED AN ER
117536	7/29/09	RED BULL ENERGY DRINK	ANXIETY, AGGRESSION	NON-SERIOUS INJURIES/ ILLNESS
123061	1/29/10	RED BULL ENERGY DRINK	MENTAL IMPAIRMENT, DYSARTHRIA, DYSPHONIA	NON-SERIOUS INJURIES/ ILLNESS
131228	8/31/10	RED BULL ENERGY DRINK	VOMITING	VISITED AN ER
136632	3/2/11	RED BULL ENERGY DRINK	CONVULSION	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), HOSPITALIZATION
139997	6/6/11	RED BULL/RED BULL SUGAR FREE	VOMITING	NON-SERIOUS INJURIES/ ILLNESS
141694	7/22/11	RED BULL ENERGY DRINK	HEART RATE ABNORMAL, ABDOMINAL PAIN, FEELING JITTERY, ANXIETY, DYSPEPSIA, ABDOMINAL PAIN, HEART RATE INCREASED	NON-SERIOUS INJURIES/ ILLNESS
142050	8/1/11	RED BULL	LETHARGY, ABDOMINAL PAIN, HEART RATE ABNORMAL	NON-SERIOUS INJURIES/ ILLNESS

Report #	Received Date	Brand/Product Name	Symptoms	Outcomes
145546	11/10/11	RED BULL ENERGY DRINK	HEART RATE ABNORMAL, SKIN DISCOLOURATION, BLOOD PRESSURE INCREASED	VISITED AN ER
149466	2/29/12	RED BULL	SYNCOPE, DEHYDRATION	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
151732	4/20/12	RED BULL ENERGY DRINK	SYNCOPE, BLOOD PRESSURE FLUCTUATION	NON-SERIOUS INJURIES/ ILLNESS
152049	5/4/12	REDBULL	CARDIAC DISORDER	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
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