U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Energy "Drinks" and Supplements: Investigations of Adverse Event Reports

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How FDA investigates adverse event reports allegedly related to energy "drinks" and supplements

FDA is continuing to investigate reports of illness, injury or death of people who took products marketed as “energy drinks” or “energy shots.”

FDA takes every adverse event report seriously, and investigates and evaluates other possible causes before deciding whether the product actually caused the medical problem. The existence of an adverse event report does not necessarily mean that the product identified in the report actually caused the adverse event. FDA assesses the relationship, if any, between a product or ingredient and the reported adverse event.

So-called “energy” products are relatively new to the market, and manufacturers of these products have labeled some as dietary supplements and others as conventional foods. FDA regulates both dietary supplements and conventional foods under the Federal Food, Drug, and Cosmetic Act (the FFDCA), but the requirements for them are different.

A food additive cannot be used in a conventional food unless it has been approved for that use by FDA. However, substances that are generally recognized as safe by qualified experts are not considered to be food additives, and can therefore be added to conventional foods without preapproval from FDA.

Dietary ingredients (the “active ingredients” in dietary supplements) require no FDA preapproval to be used in a dietary supplement, and the FFDCA requires FDA to prove that a product is unsafe under the conditions of use suggested in the labeling in order to take the product off the market.

Manufacturers, packers, and distributors of dietary supplements are required by law to report any serious adverse events to the FDA within 15 business days, and to provide (also within 15 business days) any additional medical information they obtain within a year of the adverse event report. However, the FFDCA does not require manufacturers, packers, or distributors of conventional foods to report serious adverse events to FDA. Therefore, all adverse event reports that FDA has received in connection with these products are voluntary.

It is important to note that, while those who voluntarily report an illness or injury (such as medical professionals, family members, or the consumers themselves) typically identify the product that they believe may have caused the injury or illness, FDA as a scientific public health agency must carefully investigate and evaluate other possible causes before deciding whether the product actually caused the medical problem.

While FDA investigates all reports to the best of its ability, it does not always have access to all the information needed to conclusively determine the cause of the event. Challenges include:

- reports with incorrect, incomplete or no contact information, which make following up with the complainant difficult or impossible
- variability among the completeness of the reports. Some reports may consist only of a single sentence with little detail
- reports that list the brand, but do not identify the specific product
- absence of or lack of FDA access to other information related to the report, such as medical records and medical histories (In fact, some state medical privacy laws prevent FDA from obtaining medical records related to the adverse event report.)

Complicating factors in determining the cause of a medical problem can include:

- use of other supplements or medications at the same time
- pre-existing or undiagnosed medical conditions
- improper use of the product

FDA cautions consumers that products marketed as “energy shots” or “energy drinks” are not alternatives to rest or sleep. It is important for consumers to realize that, while stimulants such as caffeine may make one feel more alert and awake, judgment and reaction time can still be impaired by insufficient rest or sleep. If you are thinking about taking one of these products, please consult your health care provider to ensure that you don’t have an underlying or undiagnosed medical condition that could worsen as a result of using them.

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 (/Safety/MedWatch/default.htm)**.

For more information:

- **Adverse Event Reports Allegedly Related to 5-Hour Energy, Monster and Rockstar (/downloads/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/CFSANFOIAElectronicReadingRoom/UCM328270.pdf)**
- **Adverse Event Reports Allegedly Related to Red Bull (/downloads/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/CFSANFOIAElectronicReadingRoom/UCM328525.pdf)**
- **Caffeine and Your Body (/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/UCM205286.pdf)**