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Editorial

Energy Drinks: Food, Dietary Supplement, or Drug?

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Recently, energy drinks/products have enjoyed increased popularity. Although commonly viewed as beverages or food products by consumers, the primary ingredient, caffeine, is considered both a food additive and a drug by the US Food and Drug Administration (FDA).[1] The caffeine content in a typical 5 ounce cup of coffee ranges from 60 to 100 mg.[1] In energy products, the caffeine content varies greatly, from 47 mg to 80 mg per 8 ounces to as high as 207 mg per 2 ounces.[2] Some of the reported adverse effects associated with energy drinks are known reactions to caffeine (eg, anxiety, nausea). However, the role of co-ingredients as risk factors or confounders has not been established. In November 2012, the FDA announced an ongoing investigation based on recent reports of significant injury or death associated with products marketed as "energy drinks."[3] Summarized data from voluntary reports received by the FDA from January 1, 2004 through October 23, 2012 revealed that adverse events ranged from nonserious (eg, nausea, vomiting, anxiety, and flushing) to significant or serious (eg, renal failure, seizures, arrhythmias, or death).[4,5] As is the case with all voluntary adverse event reporting to the FDA, data may be incomplete, causality is not definitive, under- or over-reporting may exist, and the number of reports does not indicate incidence. Yet, based on what appears to be a potential problem, investigation is warranted.

In the time before the investigation is completed and conclusions are established, health care professionals should be cognizant of the potential risks associated with these products and patients should be educated. Use in patients with underlying risk factors (eg, cardiac disorders, anxiety) or improper use may be associated with an increased potential for developing adverse events. Of particular importance is the use of these products by young people. Currently, the American Academy of Pediatrics does not recommend the use of caffeine in children because of potential harmful adverse effects and detrimental effects on development.[6] A short educational document by the FDA entitled "Caffeine and Your Body," may be a useful tool in educating parents and patients at risk.[1] In addition, health care providers (HCPs) are encouraged to query patients in routine medication histories regarding caffeine use, including beverages, nonprescription products, and dietary supplements.

To confound the issue, some energy products (eg, *5-Hour Energy*, *Monster Energy*, *Rockstar*) are marketed as dietary supplements, while others (eg, *RedBull*) are marketed as conventional foods.[4,5] Although the FDA regulates both dietary supplements and conventional foods under the Federal Food, Drug, and Cosmetic Act (FFDCA), the requirements for these products are different, including the process for marketing and reporting of adverse events post marketing. As noted by the FDA, "A food additive cannot be used in conventional food unless it has been approved for that use by the FDA. However, substances that are generally recognized as safe by qualified experts are not considered to be food additives, and therefore be added to conventional foods without preapproval from the FDA."[3] Dietary ingredients or dietary supplements also do not undergo a FDA approval process, but under the Dietary Supplement Health and Education Act of 1994 (DSHEA) manufacturers of such products are responsible for ensuring that a dietary supplement or ingredient is safe prior to marketing and that labeling is not misleading.[7] Even though the manufacturer is not required to register the product with the FDA, all processes related to manufacturing, packaging, and labeling should meet good manufacturing standards. To remove a dietary supplement from the market, the FDA must prove that it is unsafe under the conditions of the labeling.[3]

In light of the recent events and the inconsistency in labeling of energy products, it is essential that HCPs, particularly pharmacists, become involved in the education of patients regarding their use and risks. In addition, regardless of the labeling of food or dietary

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for up to 24 hours at room temperature (9°C–25°C [48.2°F–77°F]). *Lucentis* is also stable for 24 hours at room temperature. Beyond that, the company does not recommend usage and cannot provide data for storage in syringes at room temperature.

Using syringes that have been stored for prolonged periods at room temperature is risky, because product stability may be compromised. Also, in the absence of testing to confirm sterility, any inadvertent contamination will only worsen at room temperature, increasing the risk of serious eye infections such as those noted in a US Food and Drug Administration alert in August 2011 (www.fda.gov/Drugs/Drugsafety/ucm270296.htm). Incidents resulting in serious eye infections in 3 states were also published in the media in 2011 (www.ismp.org/sc?id=109 and www.ismp.org/sc?id=105). ■

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supplements, HCPs are reminded that their role is essential in the identification of adverse events related to these products with subsequent reporting to the FDA's MedWatch program.

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