



## **FACT SHEET**

### **The Facts about Caffeine in Dietary Supplements**

**Caffeine-containing products that are labeled as dietary supplements are regulated by FDA.**

- As a category of food, all dietary supplements are subject to comprehensive, robust regulation. FDA imposes Good Manufacturing Practices (GMP) regulations on supplements that are more strict than those for other food. Dietary supplements are subject to post-market surveillance through mandatory serious adverse event reporting—a requirement that does not apply to conventional foods and beverages. FDA has the authority to review dietary supplement labeling and the ability to remove a dietary supplement from the market if it poses an “imminent hazard” or “significant or unreasonable risk of injury or illness.”<sup>1</sup>
- FDA also has ample authority under the Food, Drug, and Cosmetic Act (FDCA) to demand recalls, to seize products, to detain imports or to impose civil and criminal penalties for products that are adulterated, misbranded, or that pose a safety risk to consumers.
- It is incorrect to say that energy drinks labeled as dietary supplements are beyond FDA’s reach for evaluation of their safety, or that caffeine-containing products labeled as dietary supplements are less regulated than conventional beverages. This notion is false.

**Manufacturers of liquid caffeinated products may choose to label these products as beverages or dietary supplements, but there are requirements for both, and that decision has regulatory consequences for the manufacturer.**

- By law, manufacturers are permitted to label and market liquids as conventional food (if the product is intended to be a beverage that is part of the diet, e.g., juice or soda), or as a dietary supplement (if it is intended to supplement the diet). This distinction also applies to energy drinks, although FDA does not recognize these as a unique category. These products typically contain caffeine and sometimes other added ingredients. If the manufacturer markets the product as a beverage, it will have a “Nutrition Facts” box on the label; a dietary supplement will have a “Supplement Facts” box.
- In 2009, FDA issued a draft guidance to provide criteria to help industry distinguish liquid dietary supplements from beverages and other conventional foods.<sup>2</sup> Factors such as packaging, labeling, the serving size intended to be consumed, and statements about the product in labeling or advertising can all help to determine if the product is regulated as a liquid dietary supplement or beverage. In addition, FDA’s draft guidance suggests that products packaged in cans or bottles greater than 8 oz., especially those without resealable closures, may be intended for use as a conventional food, and thus, should be labeled as a beverage. Although FDA is still finalizing this guidance, the agency’s interpretations outlined in the draft indicate that products marketed as beverages are conventional foods under the FDCA, even if the label characterizes them as dietary supplements.

<sup>1</sup> Sections 402(f)(1)(A) and (C) of the Federal Food, Drug, and Cosmetic Act.

<sup>2</sup> Draft Guidance for Industry Distinguishing Liquid Dietary Supplements from Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods (2009), <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm196903.htm>.

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- FDA evaluates products on a case-by-case basis by examining product labeling, advertising, packaging, etc., and may challenge the marketer regarding a product's representation as a conventional food or dietary supplement. FDA has issued several warning letters to firms that it believes are inappropriately marketing their products in violation of the FDCA.<sup>3</sup>

**Neither conventional food nor dietary supplement regulations specifically limit the amount of caffeine in these products—but in both cases, manufacturers must ensure safe levels of all product ingredients.**

- The Code of Federal Regulations provides that caffeine in cola-type beverages may be added at levels not to exceed .02% by volume (about 70 mg caffeine per 12 oz. can). This is the amount of caffeine considered by FDA to be “generally recognized as safe” (GRAS), and the level at which a manufacturer may use the ingredient without conducting any safety tests of its own.<sup>4</sup> It essentially sets a “safe harbor” for use, and levels of that ingredient at or below that amount are presumed to be safe; it **does not** limit how much caffeine can be included.
- This GRAS level for caffeine has been inaccurately portrayed as a limit on added caffeine in products labeled as beverages. Manufacturers of conventional food products, including beverages, may use higher levels of caffeine as long as they self-affirm the safety of those levels—meaning that they have conducted their own safety studies and assembled a panel of experts who agree with those findings. The manufacturer is not required to provide FDA with this evidence in order to use higher levels of the ingredient.
- For dietary supplements, FDA does not impose similar “safe harbor” requirements for caffeine. Under supplement regulations, ingredients like caffeine that were on the market prior to 1994 are presumed to be safe unless FDA has evidence they are not. Supplement manufacturers must be able to demonstrate that the levels of all ingredients in their products are safe, based on the label instructions (including serving amounts), or if no instructions are provided, under normal conditions of use.

**FDA regulations do not currently require any category of food products to declare the total amount of caffeine. CRN has developed recommended guidelines for the dietary supplement industry to provide consumers with this information.**

- While federal regulations require both food and supplement labels to disclose the presence of added caffeine and the quantity of all listed ingredients, the law does not require disclosure of the total amount of caffeine. Nor does it require disclosure of caffeine from naturally occurring sources. For example, the caffeine content of coffee or tea, two naturally occurring sources of caffeine, is not typically disclosed on labeling. Dietary supplements that contain a proprietary blend of herbs that may contain caffeine are similarly not required to disclose the amount, only the identity of the herbs.
- CRN has adopted recommended guidelines for its member companies to disclose the total amount of caffeine from all sources on dietary supplement labeling. CRN's guidelines also

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<sup>3</sup> See, e.g., FDA Warning Letter to Innovative Beverage Groups Holdings, Inc., 1/13/10, <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm201435.htm>; FDA Warning letter to HBB LLC dba Baked World, 7/28/11, <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2011/ucm266129.htm>; FDA Warning Letter to RockStar, Inc. DBA Livingston Chocolate Company, 5/23/12, <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm309080.htm>.

<sup>4</sup> 21 Code of Federal Regulations (CFR) § 182.1180.

recommend several advisories on labeling and encourage manufacturers to develop serving size and daily intake recommendations that are consistent with safety information about caffeine established by competent and reliable scientific evidence.

**Caffeine is one of the most studied food ingredients and has a long history of safety at a wide range of serving levels.**

- Caffeine is a safe ingredient when consumed at moderate levels, whether in a beverage or a dietary supplement. A recent FDA assessment of caffeine consumption found that most of the caffeine consumed in the U.S. comes from coffee and tea—even when energy drinks are considered. Further, FDA has also determined that for healthy adults, caffeine intake of up to 400 mg per day is not associated with negative health impacts.<sup>5</sup>
- Some recent reports have sensationalized data about adverse events associated with caffeine, but as FDA has stated time and time again, adverse event reports provided to FDA are not necessarily caused by the product. Similarly, emergency room data does not filter out likely causes of the ER visit. Further, as caffeine products are increasingly more present in the market, it follows that more people will be exposed to them, potentially leading to higher numbers of reports. However, regardless of the number of reports, the fact remains that both adverse events and ER visits should not be considered causal simply because they are reported.

**FDA has ample authority to regulate dietary supplements.**

- FDA has already taken action and issued warning letters in cases where a beverage was inappropriately labeled as a dietary supplement. FDA also has clear authority under the law to limit the levels of caffeine in any products regulated by the agency if a safety issue arises.
- FDA is currently conducting a review of the data for caffeine safety, both for adults and younger populations and those with pre-existing cardiac or other conditions.
- New laws are not needed; FDA should continue to use the array of regulatory tools available to the agency under the law to protect consumers.

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<sup>5</sup> Nawrot, P., et al., 2003, Effects of caffeine on human health. *Food Additives and Contaminants*, 20(1), 1-30.