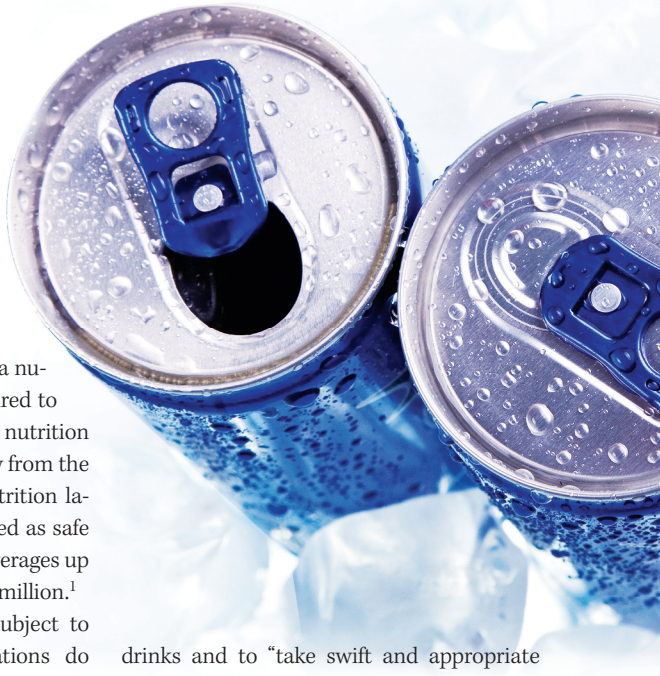
Caffeine Labeling

An industry call to action

BY JOHN E. VILLAFRANCO AND KRISTI WOLFF, KELLEY DRYE & WARREN LLP



On April 3, dietary supplement trade association the Council for Responsible Nutrition (CRN; Washington, DC) announced the adoption of new recommended guidelines for caffeine-containing dietary supplements. The guidelines urge manufacturers and marketers of finished dietary supplements that contain either naturally occurring or added caffeine to disclose a product's total caffeine content on the label and to provide certain consumer advisory statements on the labels of products that contain more than 100 mg of caffeine per serving.

In recent years, media and regulators have expressed concern about caffeine content in beverages and supplements and the potential effects of caffeine over-consumption. (Editor's note: See *Nutritional Outlook*'s January/February 2013 issue for more caffeine coverage.) This article addresses how caffeine is regulated in food and dietary supplements, recent concerns regarding caffeine content, and CRN's actions to address the topic. It also provides best-practice considerations for industry.

Caffeine Standards Differ: Supplements versus Food

FDA regulates caffeine levels in food and dietary supplements, pursuant to the Federal Food, Drug, and Cosmetic Act, but the requirements for each differ.

If caffeine is added to a food, it must be included in the listing of ingredients required on food product labels. Caffeine that is not added—i.e., caffeine that is naturally present in the product, such as caffeine naturally occurring in certain herbal ingredients—does not need to be listed as an ingredient.

Also, because caffeine—added and naturally occurring—is not considered a nutrient, manufacturers are not required to list it on nutrition facts panels. (The nutrition facts panel is considered separately from the ingredients listing portion of a nutrition label.) Caffeine is generally recognized as safe (GRAS) when used in cola-type beverages up to a level of 0.02%, or 200 parts per million.[1]

Dietary supplements are not subject to these thresholds. Current regulations do not require dietary supplement marketers to state caffeine levels on product labels. Dietary ingredients—the active ingredients in dietary supplements, such as caffeine—require no FDA preapproval to be used in a dietary supplement; instead, the Federal Food, Drug, and Cosmetic Act requires FDA to prove that a dietary supplement is unsafe under the conditions of use suggested in the labeling in order to take the product off the market.[2]

Scrutiny over Alleged Caffeine Over-Consumption

Scrutiny of advertising and labeling of energy drinks and caffeine-containing products is not new. In late 2010, FDA and the FTC sent warning letters to four manufacturers of caffeinated alcohol drinks.[3] David Vladeck, then-director of the FTC's Bureau of Consumer Protection, stated at the time, "…there is good reason to believe that these caffeinated alcohol drinks pose significant risks to consumer health and safety. Consumers—particularly young, inexperienced drinkers—may not realize how much alcohol they have consumed because caffeine can mask the sense of intoxication."[4] The agencies' letters strongly urged the companies to review the way they market their caffeinated alcohol drinks and to "take swift and appropriate steps to protect consumers."[5] In response, the manufacturers withdrew the products from the market.[6]

Scrutiny continued, however, following reports of adverse events from caffeinated energy drinks. In April 2012, Senator Richard Durbin (D-IL) called for an investigation into certain products labeled as "energy drinks" due to their caffeine content, unknown effects of certain herbal ingredients, and the fact that the products are marketed to a young audience. Sen. Durbin's call for an investigation followed the death of a 14-year-old girl from Maryland, who died of a cardiac arrhythmia due to caffeine toxicity after drinking two 24-oz energy drinks in a 24-hour period.[7]

FDA responded to Durbin's inquiry in August 2012, noting that "energy drinks" are an undefined category and may be labeled as food or dietary supplements. The agency explained the current regulations that apply to cola drinks and indicated that the agency intended to finalize draft guidance to clarify beverage labeling with respect to food or dietary supplements.[8] In response, Sens. Durbin and Richard Blumenthal (D-CT) again urged FDA to take action to limit caffeine levels in energy drinks and dietary supplements generally.[9]

In November 2012, FDA announced that it was investigating certain caffeinated energy drink brands following adverse event reports indicating as many as 13 deaths related to caffeine over-consumption.[10] To date, FDA has not made further announcements regarding the status of the investigations or any regulatory changes concerning caffeine.

CRN Urges Industry to be Proactive with Caffeine Labeling

CRN is urging member companies and industry generally to address public and regulatory concern by adopting caffeine labeling and advertising standards intended to inform consumers and promote safe use of dietary supplements. (Editor's note: Another association, the American Herbal Products Association in Silver Spring, MD, has its own recommended caffeine-labeling guidelines.)

CRN's guidelines are the product of a 20-member CRN task force that was formed last October to examine the issue. The recommended guidelines go beyond current legal requirements and address four areas:

- Dietary supplements that contain any amount of added caffeine or more than 25 mg of naturally occurring caffeine per serving should disclose the total caffeine content per serving (from both the added and naturally occurring sources) on the product label.

- Dietary supplements that contain more than 100 mg of caffeine per serving from any source should provide the following consumer advisories (or similar language) on their labels:

    - *This product is not intended (or recommended) for children and those sensitive to caffeine.*

    - *Pregnant or nursing women, those with a medical condition, and those taking medication should consult a healthcare professional before use.*

- Labeling of caffeine-containing dietary supplements should provide serving size and daily intake recommendations that are consistent with safety information about caffeine established by competent and reliable scientific evidence and should comply with all requirements of the Federal Food, Drug, and Cosmetic Act.

- Companies should not advertise, market, or otherwise promote the use of caffeine-containing dietary supplements in combination with alcohol or to counter the acute or immediate effects of alcohol.

Analysis and Best Practices

It is difficult to say whether adoption of CRN's or other industry guidelines—all attempts to help industry members voluntarily create more caffeine-content clarity for consumers—will impact future regulation of caffeine or enforcement actions related to energy drinks. The answer likely depends on industry response and compliance going forward.

If the disclosures and marketing limitations in CRN's and other guidelines are widely adopted such that reports of caffeine-related adverse events decline and the public gains greater understanding of caffeine content in energy drinks or any drink, it is less likely that the FTC or FDA would maintain its view that consumers continue to be confused, misled, or harmed by caffeine consumption.

Companies seeking to further reduce risk can limit advertising directed at young people and ensure that the disclosures used on labels are also implemented on advertising materials in a clear and conspicuous fashion. Creating greater clarity around caffeine content is a job for everyone. N

Editor's Note: Subsequent to submission of this article, on April 29, 2013, Michael Taylor, FDA's Deputy Commissioner for Foods, announced that the agency will initiate a broader investigation into the safety of added caffeine in foods. He indicated that the agency's determination that caffeine is GRAS in cola-type beverages up to a level of .02% or 200 parts per million was made in the 1950s, and, given the proliferation of products with added caffeine currently in the marketplace, the agency believes it is now appropriate to re-examine the issue.

John E. Villafranco *is a partner in the advertising and marketing practice at Kelley Drye & Warren LLP in Washington, DC. Villafranco is highly respected for offering comprehensive legal advice that emphasizes risk analysis and sound business practices for corporations involved in advertising and marketing. He can be reached at jvillafranco@kelleydrye.com.* ***Kristi L. Wolff*** *is an associate in the Washington, DC, office of Kelley Drye & Warren LLP. Having served as in-house counsel in the healthcare and food products industries, she brings a savvy business perspective to her advertising, promotions, and food and drug law practice.*

References

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2. Food and Drug Administration website, www.fda.gov/Food/NewsEvents/ucm328536.htm (accessed April 14, 2013).
3. Federal Trade Commission website, www.ftc.gov/opa/2010/11/alcohol.shtm (accessed April 14, 2013).
4. Id.
5. Id.
6. FDA website, www.fda.gov/NewsEvents/PublicHealthFocus/ucm234900.htm (accessed April 14, 2013).
7. Senator Richard Durbin website, www.durbin.senate.gov/public/index.cfm/pressreleases?ID=035e7993-a1e2-4e2c-b1a1-b4f5348eb0cb (accessed April 14, 2013).
8. Id., www.durbin.senate.gov/public/index.cfm/files/serve?File_id=17eadaa1-85e7-4ceb-a827-be244fbddfa5 (accessed April 14, 2013).
9. Id., www.durbin.senate.gov/public/index.cfm/pressreleases?ID=0ff54c20-7fa3-4398-9b53-cc55800b9360 (accessed April 14, 2013).
10. FDA website, www.fda.gov/Food/RecallsOutbreaksEmergencies/SafetyAlertsAdvisories/ucm328536.htm (accessed April 14, 2013).