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Energy drinks under the microscope

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The proliferation of energy drinks and their growing popularity especially among young adults and even adolescents has raised questions regarding whether they should be regulated and prompted recent exchanges between two U.S. senators and the U.S. Food and Drug Administration.

In a Sept. 11 letter to Margaret Hamburg, commissioner of the F.D.A., Senators Richard Durbin of Illinois and Richard Blumenthal of Connecticut expressed concerns that energy drinks with high levels of caffeine, often in combination with other ingredients that also may have stimulant effects, such as tuarine, guarana and ginseng, may be harmful to the health of young consumers. The senators urged, among other things, that the agency "assert its regulatory authority over caffeine levels in energy drinks marketed as beverages."

The F.D.A. indicated in an Aug. 10 letter to Mr. Durbin that it soon will provide a "final guidance" to industry on how to appropriately categorize and label energy drinks even as the agency continues to assess reports on health effects of high levels of caffeine.

Energy drinks have been on the F.D.A.'s radar screen for some time. In its "Draft guidance for industry: factors that distinguish liquid dietary supplements from beverages, considerations regarding novel ingredients, and labeling for beverages and other conventional foods" issued in 2009, the F.D.A. expressed concerns about two trends.

The first trend was the marketing of some energy drinks as dietary supplements "in spite of the fact that the packaging and labeling of many liquid products represent the products as conventional foods." Rules applying to the marketing of conventional foods and beverages differ from those applying to dietary supplements. All ingredients in energy drinks marketed as conventional foods must be approved food additives and substances that are generally regarded as safe (GRAS) for their intended use.

Under the Food, Drug and Cosmetic Act, a dietary ingredient intended for use in a dietary supplement does not require premarket approval and is not required to be GRAS. To restrict the use of a dietary ingredient in a dietary supplement, the F.D.A. must demonstrate that the ingredient adulterates the product because it presents an unreasonable risk of illness or injury under the conditions of use recommended in the labeling of the supplement.

The F.D.A. draft guidance noted the term "dietary supplement" means a product that, among other requirements, "is not represented for use as a conventional food or as a sole item of a meal or the diet."

The F.D.A. cautioned, "Even when the label of a liquid product characterizes it as a dietary supplement, the product may not in fact be a dietary supplement." The agency said liquid products may be repre-

sented as conventional foods as a result of such factors as their packaging, the volume in which they are intended to be consumed, their product or brand name, and statements about the product in labeling or advertising.

The second trend of concern was that some novel ingredients were being added to beverages and other conventional foods that may cause the food to be adulterated because the added ingredients are not being used in accordance with an approved food additive regulation and may not be GRAS for their intended use.

“In addition, some ingredients that have been present in the food supply for many years are now being added to beverages and other conventional foods at levels in excess of their traditional use levels or in new beverages or other conventional foods,” the draft guidance stated. “This trend raises questions regarding whether these higher levels and other new conditions of use are safe.”

In an April 3, 2012, letter to Dr. Hamburg, Mr. Durbin pointed to a report by the Substance Abuse and Mental Health Services Administration that found that between 2005 and 2009, the number of emergency room visits due to energy drinks increased ten-fold to 13,114 from 1,128.

Mr. Durbin said contributing to these hospitalizations was exceptionally high levels of caffeine in energy drinks.

Mr. Durbin noted in surveys between 30% and 50% of adolescents reported consuming energy drinks. “According to the American Academy of Pediatrics, adolescents should not consume more than 100 mg of caffeine daily,” Mr Durbin said while noting one 16-oz can of Monster energy drink contains 160 mg of caffeine.

He asked the F.D.A. to exert regulatory authority over the caffeine levels in energy drinks marketed as beverages and to investigate caffeine levels in energy drinks marketed as supplements. He further asked the F.D.A. to require manufacturers to provide “scientific evidence that ingredients such as guarana, taurine and ginseng are safe for their intended use and when used in combination with other ingredients and caffeine.”

Mr. Durbin also asked the F.D.A. to clarify the distinction between dietary supplements and conventional foods containing dietary ingredients, suggesting manufacturers were marketing some energy drinks as dietary supplements to “circumvent the safety standards required for food additives.”

In an Aug. 10 letter to Mr. Durbin, Jeanne Ireland, F.D.A. assistant commissioner for legislation, said the agency was in the process of preparing a “final guidance” that “will help both F.D.A. and industry distinguish between beverages, on the one hand, and dietary supplements, on the other.”

Ms. Ireland pointed out that the F.D.A.’s current GRAS regulation for caffeine pertains to cola-type beverages.

“Though the regulation is an affirmative statement that the specified level of caffeine in cola-type beverages is GRAS, it does not automatically preclude other uses of caffeine from being considered GRAS, nor does it automatically give GRAS status to other uses,” Ms. Ireland said. “A manufacturer that has made a determination that a food ingredient is GRAS for its intended use(s) may market that ingredient without informing F.D.A. The agency, though, may challenge such a determination.”

Ms. Ireland said the agency is reviewing recently published studies on the safety of caffeine, but the

studies to date “do not indicate any new, previously unknown risks associated with caffeine consumption.”

In their Sept. 11 letter, Senators Durbin and Blumenthal said they were pleased to learn the F.D.A. intends to release final guidance distinguishing dietary supplements from beverages. But the senators complained Ms. Ireland’s letter did not address “the potential interactions and cumulative effects of additives with stimulant properties in energy drinks with high levels of caffeine.”

They also urged the F.D.A. to consider the “unique health risks” associated with young people consuming high levels of caffeine, noting that in Ms. Ireland’s letter, she referred to caffeine intake of up to 400 mg as not being associated with any known risk to healthy adults.

“We ask the F.D.A. to include adolescents and children in their assessment of the safety risks posed by consuming high levels of caffeine, such as those in energy drinks,” the senators said.

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