For Immediate Release
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DURBIN RAISES CONCERNS WITH FDA ABOUT MELATONIN IN BAKED GOODS

Senator says FDA's authority to regulate additives in foods such as "Lazy Cakes" should be clarified

[WASHINGTON, D.C.] – U.S. Senator Dick Durbin (D-IL) today raised concerns with the Food and Drug Administration (FDA) about baked goods containing neurohormone melatonin that, because they are marketed as dietary supplements, do not require approval by the FDA for use as additives in food. Durbin asked the FDA to clarify its authority to regulate foods that contain additives, such as baked good that contain high doses of melatonin.

"Products with names such as Lazy Cakes, Kush Cakes, and Lulla Pies are marketed as dietary supplements that claim to provide a harmless way to promote relaxation, alleviate stress, and ease sleep deprivation," Durbin wrote. "The website for Lazy Cakes claims their product is, 'a delicious, chocolate alternative to medication and harmful narcotics to help you safely relax and fall asleep.' These products appear to be promoting themselves as therapeutic alternatives to medications. As such, the products may be marketed in ways that are inconsistent with federal law."

There is currently no recommended dose for melatonin supplements, but according to the Natural Medicines Comprehensive Database the typical dose should be between 0.3 and 5 milligrams. Generally each brownie and cookie contains roughly 8 milligrams of melatonin- almost double the upper limit of a typical dose.

"The inclusion of melatonin in baked goods raises numerous health concerns," Durbin noted. "The sweet, chocolaty taste may encourage consumers to eat well over a recommended quantity of melatonin. Furthermore, consumers eating these baked goods may not recognize they are consuming a neurohormone, that they should consult a doctor before eating it, and that it may not be appropriate for children, people with auto-immune diseases, or women who are pregnant or breast-feeding."

This is not the first time the FDA has been asked to clarify their authority to regulate certain dietary supplements and food additives. In January 2000, the FDA issued a 10-year plan to implement the Dietary Supplement Health and Education Act of 1994 (DSHEA), which identified the need to clarify the distinction between conventional foods and dietary supplements. Moreover, U.S. General Accountability Office (GAO) reports in July 11, 2000 and January 29, 2009 recommended FDA clarify the boundary.

[Text of the letter is below]

May 18, 2011

The Honorable Margaret Hamburg
Commissioner
U.S. Food and Drug Administration
10903 Hampshire Avenue
Silver Spring, MD 20093

Dear Commissioner Hamburg:

I write to ask the U.S. Food and Drug Administration (FDA) to issue guidance clarifying its authority to regulate foods containing dietary ingredients as additives, including baked goods containing the neurohormone melatonin.

Products with names such as Lazy Cakes, Kush Cakes, and Lulla Pies are marketed as dietary supplements that claim to provide a harmless way to promote relaxation, alleviate stress, and ease sleep deprivation. The website for Lazy Cakes claims their product is, "a delicious, chocolate alternative to medication and harmful narcotics to help you safely relax and fall asleep." These products appear to be promoting themselves as therapeutic alternatives to medications. As such, the products may be marketed in ways that are inconsistent with federal law.

The relaxing effect promoted by these products is due to the ingredient melatonin. According to scientific research there is no recommended dose for melatonin supplements, but according to the Natural Medicines Comprehensive Database the typical dose should be between 0.3 and 5 milligrams. Generally each brownie and cookie contains roughly 8 milligrams of melatonin- almost double the upper limit of a typical dose.

The inclusion of melatonin in baked goods raises numerous health concerns. For instance, the sweet, chocolaty taste may encourage consumers to eat well over a recommended quantity of melatonin. Furthermore, consumers eating these baked goods may not recognize they are consuming a neurohormone, that they should consult a doctor before eating it, and that it may not be appropriate for children, people with auto-immune diseases, or women who are pregnant or breast-feeding. According to the Office of Dietary Supplements in the National Institutes of Health, after taking melatonin people should not drive or use machinery for four to five hours, and melatonin may interact with contraceptive drugs, diabetes medications, and depressants.

These products are currently marketed as dietary supplements, therefore they do not need to establish evidence of their products' safety and effectiveness or require pre-market approval. The FDA has not approved melatonin as an additive in foods. If the FDA makes a determination that these products are foods containing a dietary ingredient additive, the manufacturers would be responsible for determining that melatonin is generally regarded as safe or failing this, the FDA would have to approve or reject melatonin as a food additive.

The distinction between dietary supplements and foods with dietary ingredient additives is not always clear, leaving room for some food products to be marketed as dietary supplements in order to circumvent the safety standards required for food additives. In January 2000, the FDA issued a 10-year plan to implement the Dietary Supplement Health and Education Act of 1994 (DSHEA), which identified the need to clarify the distinction between conventional foods and dietary supplements. Moreover, U.S. General Accountability Office (GAO) reports in July 11, 2000 and January 29, 2009 recommended FDA clarify the boundary.

Thank you for your attention to this important matter. I urge you to clarify the agency's authority to oversee the safety of foods containing dietary supplement additives.

Sincerely,

Richard J. Durbin

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