

# Lazy Cakes

## Introduction

I chose the topic Lazy Cakes because its name stood out to me. I wasn't aware of what Lazy Cakes were and I was interested to find out. Once I researched the topic and realized that they were sleep aid brownies, I became even more engaged. This was because their packaging appearance looked like a normal brownie and if I was to see this brownie around the dorm, I would have never guessed that it was medicated. Another thing that interested me was the fact that it was legal to buy a food product made with Melatonin without a prescription. My purpose of choosing this topic is to understand the natural Melatonin in our bodies, why Lazy Cakes are disapproved of by the FDA, and to figure out the purpose of why people eat these brownies.

## Section 1: Background and Problem Statement

- **Web site #1 Name: Healthy People 2020**
- **Web address:**  
<http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=38>
- **Background Information:**
  - According to the World Health Organization, good health is the state of complete physical, mental, social, and spiritual well-being and absence of injury or disease. Without sleep, none of these components can happen in an individual. For example, sleep loss and untreated sleep disorders influence basic patterns of behavior that negatively affect family health and interpersonal relationships, which would affect an individual's social (by the inability to make new relationships or have social relations), mental (dealing with the actual behavioral changes), physical (the actual stress that is put on the body after the inability to make/keep relationships and the different behavioral changes), spiritual (not being able replenish and get that positive feedback from people you love or able to go to a place a sanity because of how physically tired one is), and possibly cause injury (unable to work effectively) or disease (such as depression).
  - Sleep is necessary for many things but some of the few are to fight off infections, prevent diabetes by supporting the metabolic process, and to work effectively and safely in any activity one participates in. Therefore, lack of sleep or chronic short sleep have major effects on endocrine, metabolic, and neurological functions and if sleep patterns aren't improved, there is an increased risk of different diseases such as heart disease, high blood pressure, obesity, diabetes, and even death at all causes.
  - The goals and objectives that Healthy People 2020 have set to address the problem of sleep are to encourage more sleep health education and promote more sleep health programs. The purpose of these two strategies are to increase awareness of the importance of sleep, explain what can happen to the body without sleep, and introduce the common sleep disorders & their treatment, such as insomnia. Another purpose of these strategies is to promote better work effectiveness by teaching individuals ways to reduce risks to health and safety. Finally, these strategies would help individuals prioritize sleep over other unimportant activities that they would usually put before sleep on a given basis.

- **Web site #2 Name: Food & Drug Administration**
- **Web address:**  
**<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm266129.htm>**
- **Background Information:**
  - When an individual is unable to sleep, they go to other measures to achieve sleep. Such measures include getting prescribed medications that are laced with Melatonin. There are many forms of which Melatonin can come in, but the most recent controversy is it being in food products such as brownies. These brownies are known by many different names such as Kush Cakes and Lulla-Pies, but the most commonly known name is Lazy cakes. The FDA is attempting to take these cakes off the market because of the use of Melatonin. The FDA states that the added Melatonin isn't approved under the food additive section of their regulations.
  - The FDA also states that the product should be discontinued because of the false advertisement it gives its consumers. The FDA refers to how the creators of Lazy cakes identifies the brownies as dietary supplements and uses their supplement facts panel for nutrition labeling when there is evidence leading the consumers to believe that the brownies are conventional foods. For example, how the brownies are marketed alongside snack foods, the official Web site for Lazy cakes directs people to believe that the creators are referring to an actual cake, which is a conventional food, the product is described on their Web site as having "the same ingredients your mother uses to make brownies," which is defined as a conventional food, the uses of conventional food names to describe the product such as cakes and brownies, and finally the appearance and packaging of the product as a brownie proves it can be seen as a conventional food product.
  - Finally, the last reason why the FDA is trying to get Lazy Cakes off the market is because the FDA is not aware of the data to establish the safety of Melatonin for use as an ingredient in conventional foods. Relying on scientific literature, there have been safety concerns about the use of Melatonin. Such concerns include effects on blood glucose homeostasis, the reproductive/developmental, cardiovascular, ocular, and neurological systems. Therefore, the use of Melatonin in "Lazy Larry" products does not satisfy the criteria for GRAS status under 21 CFR 170.30.
  - The goal and/or objective of this warning letter is to raise awareness to creators of these cakes that if they don't change different details on their product, the FDA will be forced to recall them.
- **Web site #3 Name: University of Houston**
- **Web address:** **<http://www.uh.edu/af/news/June2011/ps2.htm>**
- **Background Information:**
  - Houston is one of the major places where the controversy of the Lazy Cakes is the greatest. This is because Houston has the impression that the FDA has no control over the selling of Lazy Cakes because of its consideration as being a dietary supplement. The people of Houston are concerned about the serious health risks these brownies carry even though they are legal. Mainly, the worry is the eight milligrams of Melatonin baked in each Lazy Cake, which is enough to create side effects in the healthiest adult. It's understood that Melatonin is found in very

small amounts in foods such as meats, grains, fruits and vegetables or that it can also be bought as a supplement. But when more than the usual amount of Melatonin is baked into a brownie, trouble is only awaiting to arise. Example of dangerous health risks are aimed towards children. Any added Melatonin isn't good for a child, let alone a brownie baked with eight milligrams of it. Incidences have been reported of adolescents being rushed to the hospital after biting into this brownie.

- The goal and/or objective the University of Howard is to educate people on these cakes and to warn people of the possible dangers it could have on their children and themselves.

## **Section 2: Research**

### **Web site #1 Name: Sleep research society**

- **Web address:**  
**[http://www.sleepresearchsociety.org/pdfs/Bulletin/v1\\_4\\_95.pdf#page=12](http://www.sleepresearchsociety.org/pdfs/Bulletin/v1_4_95.pdf#page=12)**
- **Summary of the research:**
  - The hormone Melatonin is important in regulation of sleep and circadian rhythm of the human body. It is a hormone that is secreted by the pineal gland. The pineal gland secretes Melatonin when it is exposed to darkness and it stops secreting when it is exposed to light. It is most commonly secreted at night. Its function is to induce sleep and can increase rapid eye movement sleep. Melatonin increases the sense of well-being and relaxation. Melatonin is also an effective treatment of sleep dysfunctions.
- **Web site #2 Name: Journal of Biological Rhythms**
- **Web address:** **<http://jbr.sagepub.com/content/20/4/291.full.pdf+html>**
- **Summary of the research:**
  - Melatonin is a tiny molecule, but it has a huge impact on biological rhythms. Its importance is just about as famous as serotonin but less known as DNA. It was reported that increased levels of Melatonin were produced during the winter. This is because the nights are longer in the winter. There was also a study that found bright lights suppress the production of Melatonin and that low doses (usually 0.3–10 mg) of Melatonin during the day can induce transient sleepiness or sleep, and lower body temperature.
- **Web site #3 Name:**
- **Web address:** **<http://jcem.endojournals.org/content/85/6/2137.full.pdf+html>**
- **Summary of the research:**
  - Melatonin is present in urine, blood, saliva, and cerebrospinal fluid. Results from different studies suggest that pre-pubertal children metabolize Melatonin faster than adults. Studies also show that the average size of the pineal gland did not differ with age (between 1 day and 15 yrs.), but the pituitary size increased by about 100%, with it being larger in girls than in boys. This is because as children grow up and are close to puberty, the pituitary grows with growth and other hormones related to puberty, making it increase in size. Once puberty is reached,

those hormones are released in bigger amounts than Melatonin usual is. This is why Melatonin is declined with the start of sexual maturation. In children and adolescents, the decrease in Melatonin could be easily linked with body weight and body surface area. But there is no such connection found in later ages of 26 and 27.

### **Section 3: Statistics**

- **Web site #1 Name: American Academy of Sleep Medicine**
- **Web address: <http://www.aasmnet.org/resources/factsheets/insomnia.pdf>**
- **Summary of the statistics:**
  - About 30 percent of adults have symptoms of insomnia. Those symptoms include fatigue, moodiness, irritability/anger, daytime sleepiness, lack of concentration, poor quality performance at school or work, lack of motivation or energy, headaches or tension, and many more. About 10 percent of adults have insomnia that is severe enough to cause daytime consequences, such as poor quality at work or school, and many others listed above. But luckily, less than 10 percent of adults are likely to have chronic insomnia. This affects the population because people unable to sleep will try to find other ways to achieve it, such as using Melatonin supplements like Lazy Cakes. This problem is getting better because people are no longer likely to have chronic insomnia and less people are affected with insomnia all together.
  
- **Web site #2 Name: Lazy Cakes Leave You, Well, Lazy**
- **Web address: <http://wfaeats.org/2011/03/04/lazy-cakes-leave-you-well-lazy/>**
- **Summary of the statistics:**
  - In 2009, about 5,000 Melatonin-related calls came in to poison control centers, most involving small children. Although none of the children have died, it was stated that there was a difficulty of waking these children up. This statistic states two messages to consumers. The first is that the product isn't safe for children. Relating back to earlier text, the Melatonin in children who haven't gone through puberty are metabolized faster, meaning that it has a faster effect than it would on children and adults who have gone through puberty. Too much of the Melatonin can cause a deeper sleep. The second message is that if too much of Melatonin can damage a child's body, it can damage an adult's body as well. Although the effects might not happen as fast as it would in a child, it was said that in large quantities, Melatonin can lead the central nervous system to slow down and cause trouble breathing. This problem is getting worse because people aren't being responsible with these lazy cakes because they are leaving them in places that are accessible to children. The adults are also taking large quantities of this product without being educated about the harm it can do to the body.
  
- **Web site #3: The Miracle of Melatonin?**
- **Web address: [http://www.acsh.org/healthissues/newsID.747/healthissue\\_detail.asp](http://www.acsh.org/healthissues/newsID.747/healthissue_detail.asp)**
- **Summary of the statistics:**
  - Melatonin has its advantages and disadvantages. Although it has been described as useful for treating or preventing jet lag, insomnia, immune disorders, cancer and the degenerative effects of aging and for the enhancement of sexual function,

it has also been known to cause harm. In a study that followed people who took Melatonin supplements, about 10 percent stated that high doses of Melatonin have caused insomnia and nightmares rather than peaceful sleep. Another study had shown individuals that developed mental impairments, while another reported severe headaches. Another important fact is that high doses of Melatonin have been found to affect other hormones such as Estrogen, testosterone and thyroid. The mass amounts of Melatonin decreases these hormones causing problems such as fatigue, infertility, and much other harm. Problems are getting worse because people are blinded by the success stories of Melatonin that they are ignoring the bigger issues that affect the body when taking the hormone over a long period of time.

#### **Section 4: Consumer Information**

- **Web site #1 Name: Alliance on Natural Health**
- **Web address: <http://www.anh-usa.org/Melatonin-cakes-and-the-backlash-on-dietary-supplements/>**
- **Summary of the information:**
  - A new fact that was learned from the Web site of Alliance on Natural Health was that there are 8 milligrams of Melatonin in one brownie. It was also stated that the standard dose in the United States and in Europe ranged from 0.3 mg to 3 mg. Another fact that was learned from this Web site was that Lazy Cakes are not considered a dietary supplement. This is because the law says that dietary supplements cannot be represented as a conventional food or as a type of a meal or a diet food and because brownies are represented as food that makes them conventional. Another interesting fact on this Web site was that the brownies are being sold in food markets and night clubs.
  
- **Web site #2 Name: National Sleep Foundation**
- **Web address: <http://www.sleepfoundation.org/article/sleep-topics/healthy-sleep-tips>**
- **Summary of the information:**
  - The National Sleep Foundation insists that not drinking alcohol before bedtime can help people go to sleep easier. This is because it disrupts sleep, causing nighttime awakenings. Another fact that was intriguing was to avoid exposure to bright light before bedtime. This is because it signals the neurons that help control the sleep-wake cycle that it is time to awaken, not to sleep. Finally, the last intriguing fact given by the National Sleep Foundation was that it is important to make a sleeping area, just a sleeping area. It is best to take work materials, computers and televisions out of the sleeping environment because those disrupt one's sleep consciously and unconsciously.
  
- **Web site #3 Name: Humane History**
- **Web address: <http://www.humane-history.org/2011/05/docs-raise-concerns-over-lazy-cakes/>**
- **Summary of the information:**
  - Melatonin can actually cause seizures in people who are predisposed to it. Also, if a woman trying to get pregnant or a man is trying to start a family, it can interfere

with their ability to start a family. Another fact is that Melatonin helps calm individuals down. It also lowers our core temperature and prepares us for sleep. It was also stated that if the lazy cakes were a necessity to take for sleep, the best results is to eat them at night. This is because it won't be as dangerous considering that it would react with the natural Melatonin in the body instead of reacting in the light of the daytime.

## **Section 5: Solutions to the Problem (or Issue)**

- **Web site #1 Name: Sleep and Sleep Disorders**
- **Web address: [http://www.cdc.gov/sleep/projects\\_partners.htm](http://www.cdc.gov/sleep/projects_partners.htm)**
- **Summary of the information:**
  - The Centers for Disease Control and Prevention is a governmental agency. The CDC is addressing the problem by collaborating with the National Sleep Foundation (NSF) to create a program called the National Sleep Awareness Roundtable. The program's purpose is to raise awareness about, increase the understanding of, and reduce the public health and safety impact of sleep deprivation and sleep disorders. The program's way of making sure this goal is accomplished is by improving communication and having more collaboration with local, state, and federal agencies, professional organizations, and the public.
- **Web site #2 Name: New Rochelle Families Organized to Curb the Use of Substances**
- **Web address: <http://nrfocus.org/2011/06/lazy-cakes-not-your-mothers-brownies/>**
- **Summary of the information:**
  - The New Rochelle Families Organized to Curb the Use of Substances is a non-profit organization whose purpose of addressing the problem of Lazy Cakes is to educate people about the truth of them. They explain how even though they have the appearance of "your mother's" brownie, they don't offer motherly advice such as not driving or operating heavy machinery after you eat one. Another important fact that isn't clearly stated is that the quantity of Melatonin used in these brownies is twice the recommended dose for an adult. This is not including the children who are persuaded by the packaging that it's a regular brownie, which ends up in the hospital because of this amount of Melatonin. Finally, the packaging is clearly designed to attract adolescents to believe that they will get a legal high which proves that the creators of Lazy Cakes aren't concern about their consumers' health, but only about their profit. By educating people about Lazy Cakes, this organization is helping people prevent or continue harm from using this product.
- **Web site #3 Name: Human Performance Resource Center**
- **Web address: <http://humanperformanceresourcecenter.org/blog/fda-seeks-to-remove-lazy-cakes-from-shelves>**
- **Summary of the information:**
  - The Human Performance Resource Center is non-profit organization who provides timely and accurate human performance information to the community. To address the problem of Lazy Cakes, their purpose was to inform the public about how dangerous Lazy Cakes were and how the FDA is seeking to remove

them off the shelves. The reasons mentioned were because of the unsafe use of Melatonin in the product as well as many other components that didn't follow the FDA regulations. The FDA gave the creators of Lazy Cakes fifteen days to respond to their letter before they banned their product for good. The Human Performance Resource Center also addressed the problem to prove to consumers that if the FDA believes that this product is unsafe, than it's something to take in consideration.

## **Conclusions**

There were many things that I learned from developing this fact sheet. I finally got the understanding of what Lazy Cakes were and I also understand where the problem from. I learned that if people received the correct amount of sleep every night, sleep aided medication wouldn't be needed. I also learned what Melatonin is and how it affects everyday life. Alongside of how it affects everyday life, I also learned where it is secreted from. The information gathered for the fact sheet has persuaded me to believe that Lazy Cakes are dangerous and are something that I will not try. To improve myself, I will get enough sleep at night so that I will never have to suffer from sleep deprivation and have to take any sleep aid medications.

---

---

<b>Back to Betty C. Jung's Web site</b>	<a href="http://www.bettyjung.net">http://www.bettyjung.net</a>
<b>Back to Fact Sheet Directory</b>	<a href="http://www.bettyjung.net/Pch202fs.htm">http://www.bettyjung.net/Pch202fs.htm</a>