



BIOS BIOCHEMICALS

1311 E. Nance St. Mesa, AZ 85203 Tel: (480) 858-0502 Fax: (480) 858-0547

APR - 2 2004

December 31, 2003

Food and Drug Administration
Office of Nutritional Products
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, DC 20204

Dear Sirs:

Notice is hereby given pursuant to the requirements of section 403(r)(6) (21 U.S.C. 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that Bios Biochemicals Corp., 1311 E. Nance St., Mesa, AZ 85203 has commenced marketing a dietary supplement bearing the following statements on the label and/or in the labeling:

(text of claim on the product label) "Slumber-EZ, Sleep Better Tonight

(text of claim on the product information sheet Are You Missing Out On Essential Sleep?

For Good Health, Sleep is Essential

You don't need science to tell you that sleep is essential to good health. Anyone who has missed even a few nights sleep can tell you how devastating sleep loss can be. People complain of a host of sleep related maladies: exhaustion, inability to concentrate and a dreadful, insidious moodiness. In addition to feeling awful, many feel their livelihood is threatened because they simply can't stay awake on the job. Resorting to stimulants to get them through the day aggravates their sleep disturbance even more.

To make matters worse, science has shown that sleep deprivation, for even a few days can mimic the physiology of depression and aging. According to the Center for the Study of Biological Rhythms at the University of Brussels, Belgium:

- Melatonin levels drop, which, ironically can make getting good sleep even more difficult.
- Cortisol levels of the sleep deprived increase in the afternoon and evening as the body attempts to carry on, even though exhausted.
- Thyroid levels increase, pushing down the levels of TSH.
- Leptin levels drop, increasing food intake and the risk for obesity.

975 0162

LET

13959

88028

The Belgian scientists conclude, " . . . a state of sleep debt, as is experienced by a substantial fragment of the population in modern societies, is likely to increase the severity of depression and widespread age-related chronic conditions such as obesity, diabetes and hypertension."

Are You At Risk?

The causes for sleep disorders are many. There are some we have little control over, but there are many others where a little prevention can be very beneficial. Some helpful steps include:

- Increasing the building blocks of serotonin in your diet by increasing consumption of eggs, avocado, cottage cheese, almonds and other L-Tryptophan rich foods.
- High lactate levels can be reduced by limiting consumption of dairy products and lactate containing supplements, such as calcium lactate.
- High cortisol levels can be reduced by treating chronic infections, including candidiasis.
- Reducing consumption of central nervous system stimulants, including
 - Caffeine from coffee, chocolate and black or green tea.
 - Guarana
 - Ephedra
- Reducing consumption of the building blocks of adrenalin, including:
 - L-Phenylalanine
 - DL-Phenylalanine
 - L-Tyrosine
- Reducing consumption of nutrients, such as L-Arginine that interfere with the production of Serotonin. L-Arginine is abundant in carob, chocolate, coconut, dairy products, meat, wheat and many types of nuts.

Dietary and lifestyle changes are helpful, but they are often not quite enough. That's where Slumber-EZ from Lidtke Technologies comes in. By providing key, sleep inducing nutrients, Slumber-EZ can carry you past the demons of sleeplessness into the arms of blissful slumber.

Are You Missing Essential Sleep Nutrients?

Building on our experience with L-Tryptophan, the scientists at Lidtke Technologies have discovered biochemical pathways and essential neurotransmitters that provide even greater sleep benefits for many people. Combining amino acids that support the neurotransmitters of the sleep pathways, minerals that help with relaxation and neurotransmitter metabolism along with vitamins that are important cofactors in the enzyme systems of sleep, Slumber-EZ addresses sleep disorders in a variety of scientifically supported ways.

- SeriGen, our proprietary amino acid blend includes amino acids: Glycine, L-Lysine, L-Serine, GABA and 5-HTP and methyl donor Trimethylglycine. This synergistic blend of inhibitory amino acids and neurotransmitters helps with relaxation and triggers a normal sleep response.

- SeriGen provides building blocks for serotonin.
- SeriGen components are associated with deeper, more restful slow wave sleep (SWS)
- Vitamin and Minerals in the Slumber-EZ formula provide essential cofactors for neurotransmitter and amino acid metabolism.

Outstanding Benefits of Slumber-EZ

- Relieves occasional sleeplessness
- Reduces early-morning awakening
- Soothes nervous irritability
- Increases more restful sleep
- Reduces next-day drowsiness
- Helps you fall asleep more quickly

Order Slumber-EZ from Lidtke Technologies

Order L-Tryptophan from Lidtke Technologies and you will receive the ideal formulation for many of the sleep disturbances that plague modern society, from the people trusted by doctors and patients in over twenty-five countries. You have our word on it. If you have questions, *Call Lidtke Technologies*. We'll put you in touch with a knowledgeable physician who can answer them.

What Happens When You Miss Sleep?

You don't need science to tell you that you can't have good health without good sleep. Anyone who has missed even a few nights sleep can tell you how devastating sleep loss is. People complain of a host of sleep related maladies: exhaustion, inability to concentrate, and a dreadful, volatile moodiness. In addition to feeling awful, many feel their livelihood is threatened because they simply can't stay awake on the job.

Resorting to stimulants to get through the day only aggravates the problem. Slumber-EZ can help break the worsening cycle of sleeplessness and exhaustion that is commonplace in our stress-filled world.

Missed Sleep Can Accelerate Aging and Disrupt Hormone Levels

Sleep deprivation for only a few days begins to mimic the physiology of depression and aging. According to the Center for the Study of Biological Rhythms, a lack of sleep not only causes fatigue and loss of cognitive function, science has recently found it also has an adverse affect on the overall health of the individual by altering 24 hour hormone profiles, increasing mood disorders and markers associated with aging.

How Does Slumber-EZ Work?

Building on our experience with the biology of sleep, the scientists at BIOS Biochemicals have researched many of the biochemical conditions that are believed to interfere with sleep, including:

- **high cortisol levels**
- **high lactate levels**
- **high norepinephrine levels**
- **high acetaldehyde levels**
- **low serotonin levels, and**
- **low GABA levels**

As science improves its understanding of the biochemistry of sleep, Slumber-EZ incorporates this understanding by targeting specific nutritional deficiencies that can keep us awake. Slumber-EZ strives to improve on the typical shotgun or chemical approach by providing what you really need, and in amounts that do the job.

Dietary and lifestyle changes are helpful, such as reducing the intake of stimulants and other unhealthy foods, but sometimes these changes are just not enough. That's where Slumber-EZ comes in. By providing sleep-inducing nutrients, the way nature intended, Slumber-EZ attacks sleeplessness in a new way.

Outstanding Benefits of Slumber-EZ

- **Relieves occasional sleeplessness**
- **Reduces middle-of-the-night wakefulness**
- **Soothes nervous irritability**
- **Increases more restful sleep**
- **Reduces next-day drowsiness**
- **Helps you fall asleep more quickly**

Order Slumber-EZ Today

Order Slumber-EZ and you will receive the ideal formulation for many of the sleep disturbances that plague modern society, from the people trusted by doctors and patients in over twenty-five countries. You have our word.

(text of claim on the product information sheet)

There is not substitute for a good night's sleep

Slumber-EZ

From the people who care enough to do it right!

There is nothing more important to good physical and mental health than a good night's sleep. BIOS Biochemicals' sleep researchers have combined the best natural sleep aids

available in the proper ratios to help overcome your occasional sleep problems.

Slumber-EZ balanced formula of 13 scientifically proven ingredients helps you:

- fall asleep quickly
- stay asleep through the night
- wake refreshed
- without next-day drowsiness

Try Slumber-EZ today,
and sleep better tonight.*

Slumber-EZ (Name of supplement)

Bios Biochemicals Corp. (brand name)

The undersigned certifies that the information contained in this notice is complete and accurate and that Bios Biochemicals Corp. has substantiation that the statement is truthful and not misleading.

Yours truly,



Pat Hallman
President