



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

2005 01 15 11 54

JAN 15 2004

Mr. Pat Hallman
President
Bios Biochemicals
1311 E. Nance Street
Mesa, Arizona 85203

Dear Mr. Hallman:

This is in response to your letters to the Food and Drug Administration (FDA), dated December 31, 2003, pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)) and 21 CFR 101.93(a).

21 CFR 101.93(a)(3) requires that the notice submitted pursuant to 21 U.S.C. 343(r)(6) and this section be signed by a responsible individual who can certify the accuracy of the information presented and contained in the notice, and that the individual certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading. Your submission does not meet this requirement in that the notice does not contain the signature of a responsible individual who is certifying that the firm is in compliance with the requirements of the Act and the regulation. Therefore, your firm has not complied with the notification requirement in 21 U.S.C. 343(r)(6) and must submit notifications in accordance with the requirements in 21 CFR 101.93(a). The failure to submit a valid notice as required by the Act and the agency's regulation may subject your product to regulation under the drug provisions of the Act.

Your submission states that Bios Biochemicals is making the following statements, among others, for the products **ViroStat** and **Defend**:

"Challenges to your immune system are everywhere...Cold and flu season..."
Take extra DEFEND! [ViroStat] when your immune system is challenged by...Colds & flu season..."for adults, children and animals."

You also state that the product **Slumber-EZ** is prevent, among other things, sleep deprivation that "is likely to increase the severity of depression and widespread age-related chronic conditions such as obesity, diabetes and hypertension."

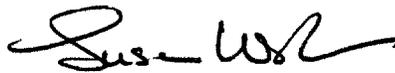
704

Page 2 - Mr. Pat Hallman

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate diseases, namely, the common cold and influenza and diseases that may be associated with sleep deprivation. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,



Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Los Angeles District Office, Compliance Branch, HFR-PA240

Page 3 - Mr. Pat Hallman

cc:

all w/copy of incoming

HFA-224

HFA-305 (docket 97S-0163) ✓

HFS-800 (file)

HFS-810 (Walker)

HFS-811 (Moore w/original incoming)

HFD-40 (Behrman)

HFS-607

HFV-228 (Benz)

GCF-1 (Nickerson)

f/t:rjm:HFS-811:1/13/04:86961.adv.disc82

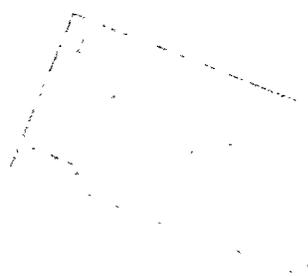


BIOS BIOCHEMICALS

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

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.

1/1/04

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 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.*" (italics added)

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



BIOS BIOCHEMICALS

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

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) "ViroStat Protect Your Health, Immunity is Essential for Survival"

(text of claim on the product information sheet) "Immunity is Essential For Survival"

Immunity is everything you imagined – and more!

Your immune system is one of the most complicated, yet elegant systems in the entire universe. With its dozens of members and systems, it surely rivals the internet for complexity. But, even with all its complexity, we are learning each day new and proven ways to make it work better - ways that go far beyond Echinacea and Golden Seal – popular immune enhancers of the 70's.

What is immunity anyway?

Though we often talk about the immune system, it is rarely fully understood. According to the Merck Manual, a guide book for physicians, the function of the immune system, "is to distinguish entities within the body as "self" or "non-self" and to eliminate those that are non-self." In other words, to determine what is "me" and what is not. Anything that is not "me" is called an "antigen." Though scientists spend a lifetime and learn only a tiny part of the immune system in detail, you can learn enough if you think of the immune system as the members of an extended family.

- 1961

- **T-cells** - our butler at the door. He decides who belongs and who does not.
- **B-cells** - wise old uncle B. He knows just how to deal with each intruder.
- **MHC** - dear old aunt M. She can recognize family members with just a touch.
- **Macrophages, neutrophils and natural killer cells** are the Dobermans at the gate - and a few ferocious family cats. They gobble up anyone who doesn't belong - but only if uncle B or aunt M tells them to.
- **Cytokines**: they scurry about the place like children at a wedding - carrying urgent messages like:
 - "Someone I don't recognize just went into the garden."
 - "This one is not a member of our family."
 - "Get these intruders out of here."

How does VIROSTAT boost immunity?

As with a family, the secrets to powerful immunity are order and cooperation. Each member of the immune system family is ideally suited to its task. And when all work together with perfection, your immune system becomes unbeatable. VIROSTAT has everything you need to:

- **Strengthen each member**
- **Improve communication**
- **Increase cooperation**
- **And keep a clean house as well**

Cellular Good Housekeeping - One of the keys to unbeatable immunity

We've all seen that families with clean and orderly homes are often more efficient than those who stumble over debris and struggle just to move around. Your immune system needs space in which to work, but when the immune cells go to work, they often make a mighty mess. Like a carpenter remodeling a kitchen, or dogs and cats run amok at an outdoor wedding, the mess can quickly grow so huge that you can hardly move. Fortunately, ViroStat has powerful ingredients that "pick up," "clean up" and "sweep up" the mess at a cellular level - preventing the clutter that can choke your immune system.

Communication and cooperation - Together we can overcome anything

When your immune system is activated, cytokines carry messages from cell to cell at an amazing rate. Making sure that each message is the "right" message and gets to the "right" cell is as far more complex than any corporate switchboard. Fortunately, ViroStat helps shepherd each message to the cells that need to know - guarding the message against the wolves along the way while at the same time nourishing the messenger. With ViroStat in your system, you can be sure that scientifically proven ingredients are supporting your immune system at every level.

Challenges to your immune system are everywhere

- **Day care centers**
- **Airplane travel**

- Public Restrooms and gyms
- Movie theatres
- Air and water pollution
- Cold and flu season
- Cafeterias and salad bars

Isn't it worth three capsules a day . . .

To be sure you're at your best.

- ViroStat improves immune system communication
- ViroStat boosts immune system cooperation
- ViroStat cleans house at a cellular level
- ViroStat enhances immunity
- ViroStat helps your immune cells thrive

. . . but only if you give it a try. Order *ViroStat* from *Lidtke Technologies* and you will receive a clinically tested product to strengthen your immune system. If you have questions, *Call Lidtke Technologies*. We'll put you in touch with a knowledgeable physician who can answer them.

(text of claim on the product information sheet)

Protection as sure as a good mom and dad

ViroStat

From the people who care enough to do it right!

ViroStat boosts immunity and protects against common pathogens. Make ViroStat part of your family's defense against the colds and flu season. The scientifically tested ViroStat formula is great for everyday protection. Take extra ViroStat when your immune system is challenged by:

- Colds & flu season
- Day care centers
- Bus & airline travel
- Movie theatres
- Public restrooms & gyms

Isn't your family's health worth three capsules a day?

Don't let "the bug" get in your system!

ViroStat

From the people who care enough to do it right!

ViroStat boosts immunity and protects against common pathogens. Make ViroStat part of your family's defense against the colds and flu season. The scientifically tested ViroStat formula is great for everyday protection. Take extra ViroStat when your immune system is challenged by:

- **Colds & flu season**
- **Day care centers**
- **Bus & airline travel**
- **Movie theatres**
- **Public restrooms & gyms**

Isn't your family's health worth three capsules a day?

ViroStat (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**