



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

2004 APR 22 10:00 AM

APR 22 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, and received by FDA on April 2, 2004, 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). The letters appear to be in further response to our letter to you dated January 15, 2004.

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

“ViroStat boosts immunity and protects against common pathogens. Make ViroStat part of your family’s defense against the colds and flu season.”

“DEFEND! boosts immunity and protects against common pathogens. Make DEFEND! part of your family’s defense against the colds and flu season.”

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 other diseases caused by pathogens. 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.

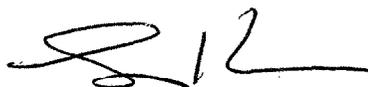
975-0163

LET 752

Page 2 - Mr. Pat Hallman

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'SJW', with a long horizontal line extending to the right.

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

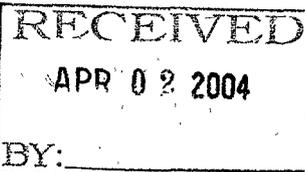
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Los Angeles District Office, Compliance Branch, HFR-PA240



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.

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- 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
- 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 *Lidtko Technologies* and you will receive a clinically tested product to strengthen your immune system. If you have questions, Call *Lidtko 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:

- 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!

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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**



BIOS BIOCHEMICALS

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

December 31, 2003

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Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, DC 20204

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

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. . . but only if you give it a try. *Order DEFEND! 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)

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

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Bios

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Defend! (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