



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

DEC 27 2000

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Ms. Eileen Venum, RAC
Vice President of Regulatory Affairs
Mannatech, Inc.
600 S. Royal Lane
Suite 200
Coppell, Texas 75019

Dear Ms. Venum:

This is in response to your letter of November 27, 2000 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Mannatech, Inc. is making the following claim, among others, for the product ImmunoStart™:

“Supporting your mucous membranes...since the majority of invaders on your body must pass through these defenses...first line of defense...turning them into the body’s own powerful, natural antimicrobial wash”
“...begin the fight against bacteria...”
“...discourage growth of bad bacteria”
“...cells on patrol against invaders”
“...unwanted viruses work around your system failures, microbes make themselves at home and toxins take hold”
“Fight infection and disease”
“...starves bad bacteria”
“...destroy bacteria”

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 this product suggest that it is intended to treat, prevent, cure, or mitigate diseases caused by pathogenic microorganisms. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is 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, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

LET 437

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Please contact us if we may be of further assistance.

Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
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, Dallas District Office, Office of Compliance, HFR-SW140

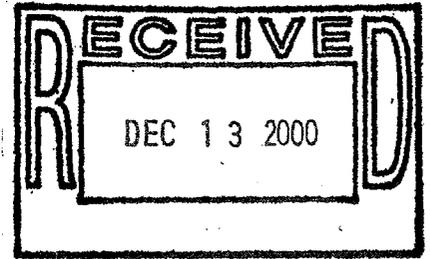
cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-800 (r/f, file)
HFS-810
HFS-811 (file)
HFD-40 (Behrman)
HFD-310
HFD-314 (Aronson)
HFS-605
HFV-228 (Benz)
GCF-1 (Dorsey, Nickerson)
f/t:HFS-811:rjm:12/15/00:docname:73704.adv:disc53



November 27, 2000

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204



Re: Statements of Nutritional Support Notification

Dear Sir or Madam:

In accordance with 21 U.S.C. § 343(r) and 21 CFR § 101.93, Mannatech Incorporated, 600 S. Royal Lane, Ste 200, Coppell, TX 75019, hereby submits an original and two copies of its notification within 30 days of first marketing its product with the statements presented below.

Supplement Brand Name: ImmunoStart™

Supplement Ingredients: Bovine colostrum
Beta (1-3), (1-6) glucans
Lactoferrin
Citrus pectin

Text of Statement of Nutritional Support:

ImmunoStart™ provides daily support for strong immune systems.

Included with the submission is the entire text of the ImmunoStart™ labeling for your review.

Mannatech Incorporated certifies that it possesses adequate substantiation for these statements of nutritional support; that the substantiation renders them truthful and non-misleading and thus permissible under the Dietary Supplement Health and Education Act (DSHEA); and that the information contained in this notice is complete and accurate.

Sincerely,

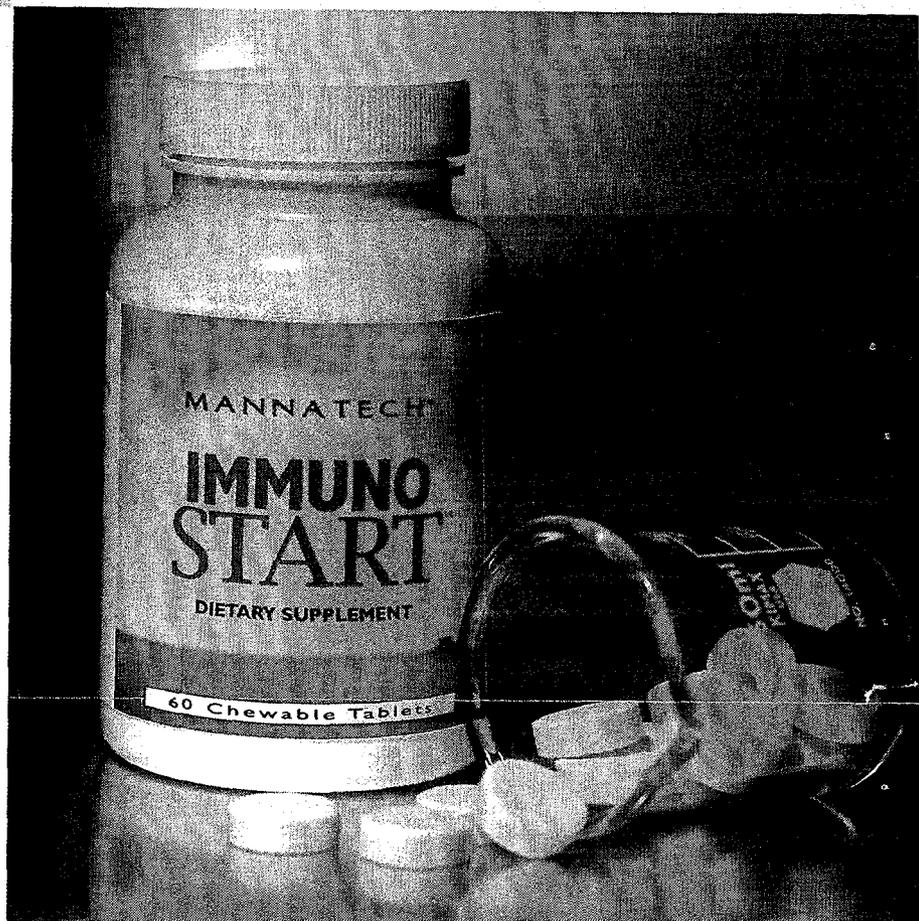
Eileen Vennum, RAC
Vice President of Regulatory Affairs

ImmunoStart™ Chewables

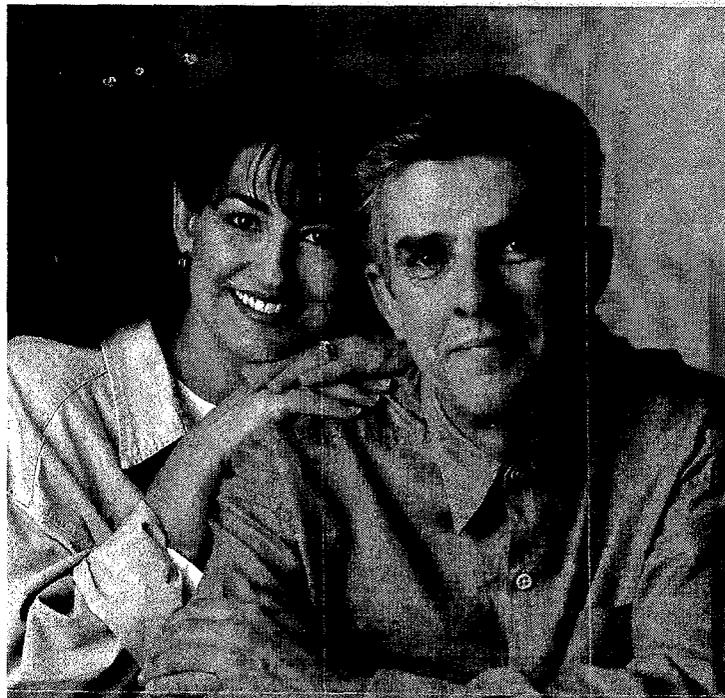
A Fresh Start for Your Immune System

Key Immune Health Benefits

- Fast-acting.
- Energizes a cascade of immune responses that begin in the mouth and proceed throughout the body.
- Optimizes response of natural killer cells, B-cells and T-cells which seek out and destroy foreign substances.
- Reacts with the specific cell receptors that cause the cells to engulf and destroy bacteria and cellular debris.
- Strengthens the mucosal immune system, your first-line defense.
- Supplies and enhances natural antibodies (immunoglobulins).
- Helps regulate the number and activities of circulating immune cells.
- Initiates communication in the immune system which releases chemical messengers to fight infection and disease.
- Supports immune cell growth and proliferation in the GI tract.
- Binds iron so that it starves bad bacteria throughout the body – re-routing it to become more bio-available for beneficial uses.
- Helps the body remove heavy metals and toxins in the cells.
- Contains proteins that are combined with saccharides to make glycoproteins for hormones and enzymes used in immune regulation.
- Helps balance the immune system.
- Features Prime Colustrum®, Beta Right™, lactoferin and citrus pectin.



Mannatech
INCORPORATED



ImmunoStart™ provides daily support for strong immune systems.

Energize Your Immune System

ImmunoStart™ chewables feature a targeted array of nutrients for building and nurturing immune health, especially when stress tends to bear down on it.

The immune system is one of the body's most complex systems with defenses throughout your body. However, your mouth is perhaps the prime entry point.

That's why the uptake and immune system activities of nutrients from ImmunoStart™ begin in your mouth as they are chewed and continue in a cascade of immune responses throughout your immune system.

Optimize Your First-Line Defenses

Supporting your mucous membranes that line your mouth, nose, lungs and digestive tract is very important since the majority of invaders on your body must pass through these defenses.

These membranes comprise the largest barrier in the body and form your first line of defense. When the mucosal immune response is triggered, it makes natural antibodies. These antibodies "arm" saliva, tears, bronchial and nasal secretions, as well as fluids in the digestive tract, turning them into the body's own powerful, natural antimicrobial wash.

When You Want Immune Support *Right Now.*

Specialized nutrients in ImmunoStart™ chewables can immediately react with mucus membranes in the mouth and esophagus to energize your immune system and begin the fight against bacteria. They bind to specific receptor sites that send signals directly to your lymphatic system — the *roadway for your trillion circulating white blood cells on patrol against invaders.*

The nutrient forces in ImmunoStart™ chewables spread throughout the gastrointestinal (GI) tract where they facilitate normal cell proliferation, growth of beneficial GI bacteria, and discourage growth of bad bacteria. That's important, because one of the major subdivisions of the immune system is the lymphatic tissue in the GI tract.

Life in The 21st Century May Require Extra Immune Support.

Everyday stresses such as work, traffic, and taking care of a family can accelerate your body's use of nutrients. Add on days when you don't eat right and nights when you don't get enough sleep and sooner or later your immune system finds it difficult to keep up with demands placed upon it.

When your immune defenses aren't prepared, unwanted viruses work around your system failures, microbes make themselves at home and toxins take hold. The responsibility for your immune system is in your daily care. What kind of protection can it provide if you neglect it?

Emotional stress is a silent threat to good health. While you recognize its signs, you may often fail to acknowledge the burden it places on your body. And, even when you know you are physically stressed, whether from work or a workout, you often think, "well, I just need to rest." But that may not be all your immune system needs to bounce back.

You may fail to recognize the environmental stress your body incurs that can make your immune system work harder, or the dietary stress caused by making poor food choices. To help combat environmental stress ImmunoStart™ chewables support the body's ability to do cellular "house cleaning." It helps your body to remove heavy metals, toxins and damaged cellular material from cells.

To help the body handle physical stress, ImmunoStart™ features peptides, amino acids and glycoproteins that engage your body's natural ability to heal and repair itself.

ImmunoStart™ Provides the Perfect Protein Complement to Glyconutrients

Components in ImmunoStart™ help trigger a cascade of immune signaling mechanisms. This is especially important when stress factors work against your immune system. Glyconutrients help carry these immune signals to other cells. The combination of ImmunoStart and Ambrotose® complex provide a synergistic array of proteins, peptides, polypeptides, and glycoproteins—nutrients that can help you achieve optimal health through an appropriately immunomodulated immune system.

Protected by U.S. patents 5,576,015, 5,519,009, 5,397,773, 5,705,184, and 5,702,719. Other U.S. and Canadian patents pending.

Beta Right™ is a trademark of Biopolymer Engineering, Inc.
Prime Colostrum® is a registered trademark of Immuno-Dynamics Inc.