



AUG 24 2001

Mr. Mark F. Sever
President
European Lifestyle Products, LLC
P. O. Box 1345
Gibsonia, Pennsylvania 15044

Dear Mr. Sever:

This is in response to your letter of August 8, 2001 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 European Lifestyle Products, LLC is making the following claim, among others, for the product **Polyerga Plus™**:

“...produces the white blood cells that defend the body against infection.”

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 statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate a disease, namely infectious disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests 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 539

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Please contact us if you require 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

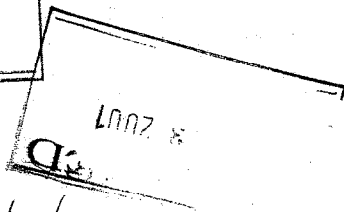
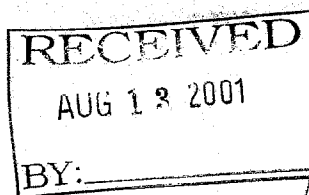
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Philadelphia District Compliance, HFR-MA140

Overnight Mail

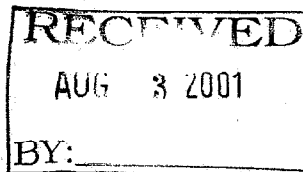
August 8, 2001

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



Ref: Polyerga Plus™ Dietary Supplement

Dear Sir and/or Madam:



This is a notification pursuant to Section 403(r)(6)(C) of the Federal Food, Drug, and Cosmetic Act that European Lifestyle Products, LLC, Gibsonia, Pennsylvania 15044, has, within the past 30 days, begun marketing its immune system booster product "Polyerga Plus™" using the following statements:

- The spleen, an organ in the lymphatic system, performs many different blood cell related activities. The spleen produces the white blood cells that defend the body against infection. It also stores, destroys or recycles red cells and platelets as needed. The human spleen releases several substances that activate the immune system. The most active compounds are small peptides.
- Polyerga Plus™ contains oligo- and polypeptides from porcine spleen that provide nutritional ingredients to support health.
- Polyerga Plus™ has, for more than 50 years, improved energy levels and the general sense of well-being.
- Polyerga Plus™ appears to contain immune system activators that support the natural immune system.

These statements are made for a dietary supplement containing a proprietary blend of porcine spleen peptides. Inactive ingredients include sucrose, talc, microcrystalline cellulose, calcium carbonate, clay, polyvinyl pyrrolidone, powdered cellulose, acacia, shellac, corn syrup, titanium dioxide, magnesium stearate, cornstarch, silicon dioxide, ferric oxide, polyethylene glycol (MW 6000), montan glycol wax, castor oil, polyoxylated castor oil, lactose, gelatine, rapeseed oil, glycerin, partially hydrogenated soybean oil, beeswax, hydrogenated soybean oil, lecithin, water, dibutylphthalate and hydroxypropyl methylcellulose phthalate.

P.O. Box 1345 Gibsonia, PA 15044 724-934-3068 FAX 724-934-9181

Product Package
Approx 80% of Actual

Polyerga[®]
Plus

Polyerga[®]
Plus

Supplement Facts

Serving Size One (1) Tablet or Capsule

Amount Per Tablet	Amount Per Capsule
Oligopeptides and Polypeptides from porcine spleen extract 100mg*	Oligopeptides from porcine spleen extract 100mcg*

*Daily Value not established.

OTHER INGREDIENTS: Tablet - Sucrose, talc, microcrystalline cellulose, calcium carbonate, clay, polyvinyl pyrrolidone, powdered cellulose, acacia, shellac, corn syrup, titanium dioxide, magnesium stearate, cornstarch, silicon dioxide, ferric oxide, polyethylene glycol (MW 6000), montan glycol wax, castor oil, polyoxylated castor oil, and sodium lauryl sulfate.
Capsule - Lactose, gelatine, rapeseed oil, glycerin, partially hydrogenated soybean oil, beeswax, hydrogenated soy bean oil, lecithin, water, titanium dioxide, dibutylphthalate, hydroxypropyl methylcellulose phthalate, and ferric oxide.

Distributed by European Lifestyle Products, LLC
P.O. Box 1345
Gibsonia, PA 15044

Made In Germany

HORFERVIT
PHARMA GMBH

Polyerga[®]
Plus

A Dietary Supplement

Polyerga[®]
Plus

DIRECTIONS FOR USE: For individuals 18 years of age or older, take as recommended below.

Tablets: Take one (1) tablet three (3) times daily before meals.

Capsules: Take additionally one (1) capsule every other day before a meal.

Store in a cool (not above 75°F) dry place.

KEEP OUT OF REACH OF CHILDREN.

WWW.EUROPEANLIFESTYLEPRODUCTS.COM



HORFERVIT
PHARMA GMBH

Polyerga[®]
Plus

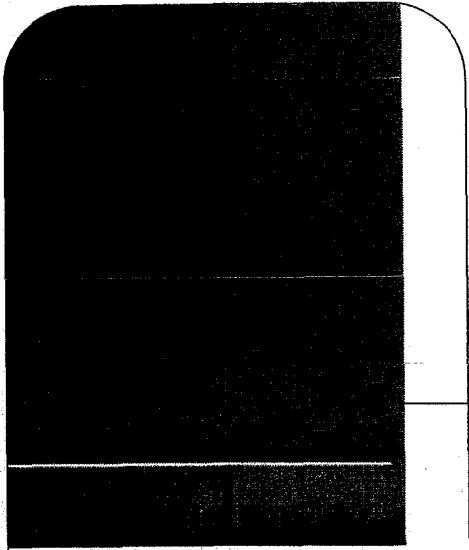
A Dietary Supplement

Polyerga[®]
Plus

Batch
EXP

Part No.: TN HFFV 01001

Display Box
Approx. 50% of Action 1



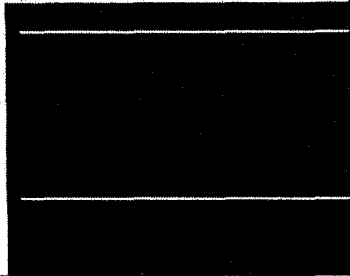
Polyerga[®]
Plus
A Dietary Supplement



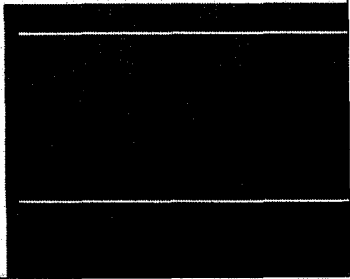
Contains 4 Boxes
Store in a cool (not above 75°F) dry place.
Distributed by European Lifestyle Products, LLC
P.O. Box 1345
Gibsonia, PA 15044
Made in Germany



Polyerga[®]
Plus
A Dietary Supplement



Polyerga[®]
Plus
A Dietary Supplement



POLYERGA PLUS™

*"Purified and specially processed
peptides from porcine spleen"*

- **The spleen, an organ in the lymphatic system, performs many different blood cell related activities. The spleen produces the white blood cells that defend the body against infection. It also stores, destroys or recycles red cells and platelets as needed. The human spleen releases several substances that activate the immune system. The most active compounds are small peptides.**
- **Polyerga Plus™ contains oligo- and polypeptides from porcine spleen that provide nutritional ingredients to support health.**
- **Polyerga Plus™ has, for more than 50 years, improved energy levels and the general sense of well-being.**
- **Polyerga Plus™ appears to contain immune system activators that support the natural immune system.**

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.