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OCT 11 2006

Dr. Edward Group
Global Healing Center, Inc.
2040 North Loop West
Suite 108
Houston, Texas 77018

Dear Dr. Group:

This is in response to your letter of September 27, 2006 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 Global Healing Center, Inc. is making the following claims for the product **Paratrex™** :

“[C]reates an environment hostile to parasites.”

“The safe way to protect against these health destroying invaders...Since most parasites entrench themselves in the digestive system and colon, it makes sense to create an environment that’s NOT friendly for parasites.”

“Paratrex™...aids in helping the body establish an internal environment that is unfavorable and even hostile to...parasites.”

“Paratrex™ ...producing an environment that is inhospitable to parasites.”

“[P]roduce an extremely unfavorable environment for the establishment of invading parasites and worms....”

“Black walnut...hostile to parasites.”

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, or mitigate a disease, namely, those characterized by infection with parasites. 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, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

979 0163 LET 907

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Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Vasilios Frankos".

Vasilios H. Frankos, Ph.D.
Acting 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-310

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

FDA, Dallas District Office, Office of Compliance, HFR-SW140

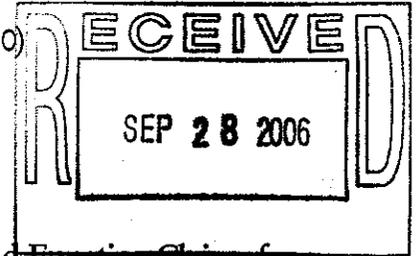


Rodriguez O'Donnell Ross Fuerst
ATTORNEYS & COUNSELORS AT LAW

Benjamin L. England, Esq.
202.973.2984
benland@rorfgw.com

September 27, 2006

Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy
College Park, MD 20740



Re: Global Healing Center, Inc.'s Notification of Structure and Function Claims for
Paratrex™ Under 21 C.F.R. 101.93

Dear Sir or Madame:

We represent Global Healing Center, Inc. Please find attached an original and three copies of a notification of structure and function claims for Paratrex™, pursuant to 21 C.F.R. § 101.93(r), which we submit to you on behalf of Global Healing Center, Inc.

Please sign and date one of the three copies of the notification and return it to my attention as evidence of our filing of this notification. You may use the enclosed envelope and airway bill to return the dated and signed copy.

If you have any questions, please do not hesitate to contact me directly.

Very truly yours,

Benjamin L. England, Esq.
Rodriguez O'Donnell Ross Fuerst
Gonzalez Williams & England, P.C.

Cc: Dr. Edwin Group, Global Healing Center, Inc.
File

06-7472

September 26, 2006

Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy
College Park, MD 20740

Re: **Notification of Structure and Function Claims for Paratrex™ Under 21 C.F.R. 101.93**

Dear Sir/Madam:

Pursuant to 21 CFR 101.93, Global Healing Center, Inc., hereby notifies you that it has included structure and function claims for its dietary supplement Paratrex™ on its website <http://www.ghchealth.com/paratrex.php> and the product label. This notice is provided in compliance with regulations promulgated and enforced by the U.S. Food and Drug Administration. Global Healing Center intends to fully comply with all FDA requirements respecting the labeling, marketing and distribution of its dietary supplements. If you have any concerns regarding this notice or its contents, please contact the undersigned immediately.

Global Healing Center, Inc., is the distributor for Paratrex™ and its address and contact information are as follows:

Global Healing Center, Inc.
2040 North Loop West
Suite 108
Houston, TX 77018
Phone: 1-713-476-0016
Email: drgroup@ghchealth.com

Structure or function, or general health and well being claims made for Paratrex:

1. "Get Paratrex™ and promote a natural cleansing of your system. Paratrex™ creates an environment hostile to parasites. Flush your system clean!"
2. "Get Paratrex™ and promote a natural cleansing of your system
 - Paratrex™ helps flush your system clean
 - Promotes a hostile environment for unfriendly invaders"



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Phone: 281.471.0018 | Fax: 281.471.0017 | Web: www.globalscience.com

3. "The safe way to protect against these health destroying invaders is to pay close attention to the causes listed above. Since most parasites entrench themselves in the digestive system and colon, it makes sense to create an environment that's NOT friendly for parasites."
4. "Paratrex™ formula is designed to help promote the cleansing, detoxification, and flushing of your entire intestinal track. Paratrex™ is a comprehensive combination of nine, all-natural ingredients that have been proven to promote intestinal health."
5. "Paratrex™ is one of the most powerful aids in helping the body establish an internal environment that is unfavorable and even hostile to harmful organisms and parasites".
6. "Paratrex™ is a unique formula designed to help the body detoxify and flush your intestinal track, Parasites may be present in food or in water and can cause disease."
7. "Paratrex™ also aids the body in creating an in-hospitable environment for invading organisms."
8. "Paratrex™ is one of the most powerful aids in helping the body fight against an invasion by harmful organisms using wild-crafted herbs. . . . The herbs used in Paratrex™ are traditionally known to aid the body in producing an environment that is inhospitable to parasites."
9. "The razor sharp edges of the diatoms in Diatomaceous Earth discourage establishment of parasites in the intestinal tract. This ingredient has been used to promote intestinal health and to help the body in its fight against intruders without the use of chemicals. Because of its sharp edges, this ingredient helps produce an extremely unfavorable environment for the establishment of invading parasites and worms in the intestines."
10. "Ancient Greeks and Romans used Black Walnut Hull to promote intestinal health and beneficial microbial activity. Asians have also used the kernel and the green hull to help promote the cleansing of the intestinal tract. The high tannin content of this ingredient is primarily responsible for its beneficial properties,



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Natural Health Food Organics, LLC

although other constituents such as juglandin, juglone and juglandic acid are most likely involved. Black Walnut is thought to have the ability to oxygenate the blood, which is a condition thought to be hostile to parasites. The green husk contains organic iodine. Iodine is known to have properties which help produce an intestinal environment hostile to harmful bacteria. Black Walnut has been used to promote healthy sugar levels, to help melt away fatty materials, and to detoxify the colon. Black Walnut is also useful for helping maintain an internal condition that is unfavorable to fungi."

11. "The active ingredient (citricidal) of grapefruit seed extract has been known to have the unique ability to safely and effectively help boost body health. Citricidal is said to effectively help create an environment that is not friendly for body invaders."

12. "Historically wormwood has been used as an intestinal cleanser and a medicinal herb. References to Wormwood go back as far as 1600 BC in Egypt. In Paratrex™ it helps create an extremely hostile environment for certain parasitic invaders. It has also been known to promote normal digestive processes and helps increase secretions of the liver and gallbladder."

13. "According to history, Male Fern Root has been used for centuries as a medicinal herb to promote digestive health and as an aid in cleansing body systems. Researches have determined that the oil of the male fern root contains the chemicals filicin, filmarone, and oleoreson. These chemicals help establish an intestinal environment that is toxic and debilitating to certain intestinal invaders helping promote digestive health."

14. "The oil of chenopodium, derived from the seeds and other overground parts of wormseed, is an excellent ingredient for any product designed to promote an intestinal environment that is unfavorable to intruders. Before being popularized in the 19th century in America by the medical establishment, American Worm Seed was frequently used by the American Indians to promote digestive health. Wormseed is also said to have properties that help remove intestinal irritants to the colon wall that can cause spasms. Wormwood contains up to 90% ascaridol, an ingredient that is very useful for promoting a hostile environment to would be intestinal intruders."



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15. "Bromelain was first introduced in 1957 as an important proteolytic enzyme that supplements the body's natural enzymes. Bromelain, like all proteolytic enzymes, decomposes harmful proteins in the body. Scientific literature contains over 600 research articles about Bromelain. It is derived from the pineapple plant and is useful in supporting the body's natural recovery mechanisms following physical stress occurring during sport and strenuous sport activities and as an aid in digestion."

16. "Wild-Crafted Kamala (*Mallotus Philippinensis* {MUELL.}) - Greatest use is for helping to cleanse and flush the intestines of harmful substances. It is known to act quickly and effectively."

17. "Organically Certified Clove - Has been used for many years to help aid the body. It's believed to have natural detoxifying actions and to help promote an environment hostile to harmful intestinal bacteria."

18. "Colon - It is also suggested that you keep the bowels moving and the colon as clean as possible. Using Oxy-Powder™ every other evening while taking Paratrex™ will help to accomplish this. Because of Oxy-Powder's oxygenated melting action upon compacted fecal matter, using both products may promote the safe removal of toxins and any harmful residents that may be lurking in unwanted waste from the intestines."

Paratrex™ Ingredients

The ingredients of Paratrex™ are:

- Organic Diatomaceous Earth
- Organically Certified Black Walnut from Green Hull
- Organically Certified Grapefruit Seed Extract
- Organically Certified Wormwood
- Wildcrafted Male Fern Root
- Wildcrafted American Wormseed
- Bromelain
- Wildcrafted Kamala
- Organically Certified Clove
- Kosher certified vegetarian capsules

Certification

Dr. Edwin Group, President of Global Healing Center, Inc., hereby certifies that the information presented and contained in this Notice is complete and accurate



GLOBAL HEALING CENTER

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713.261.1111 | www.globalhealingcenter.com

structure and function claims made on the label or in the labeling of Paratrex™ and that Global Healing Center, Inc., has substantiation that each statement is truthful and not misleading:

Dr. Edward Group

A handwritten signature in black ink, appearing to read 'Edward Group', written over a horizontal line.

Date:

Encl. two copies attached