

**EARTHRISE**

**Earthrise Nutritionals, LLC**

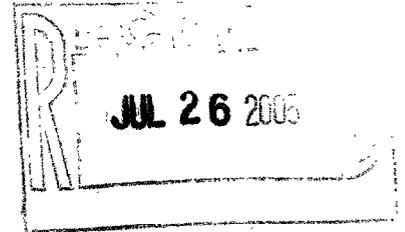
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July 22, 2005

Susan J. Walker, M.D., Director,  
Division of Dietary Supplement Programs (HFS-810),  
Center for Food Safety and Applied Nutrition,  
Food and Drug Administration,  
Department of Health & Human Services  
5100 Paint Branch Parkway,  
College Park, MD 20740



**Re: Notification of Structure/Function Statements –  
Earthrise® Spirulina Digest & Flora® Dietary Supplement**

Dear Dr. Walker,

As per 21 CFR section 101.93, this letter is a notification of new structure/function claims to be made on labels, brochures and collateral materials of the following Earthrise Nutritionals dietary supplement:

Earthrise® Spirulina Digest & Flora® Capsules.

The structure-function statements are listed on the enclosed attachment.

Manufacturer/Packer/Distributor: Earthrise Nutritionals, LLC.

The firm believes it has substantiation, and the structure-function claims are appropriate, truthful and not misleading. If you have any questions or concerns, please do not hesitate to contact me at (760) 348-5027 extension 321.

Sincerely yours,

Amha Belay, Ph.D.  
Senior Vice President/Scientific Director

Enclosure

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July 22, 2005

**Structure/Function Statements For Earthrise Nutritionals, LLC.**  
**Earthrise® Spirulina Digest & Flora® Dietary Supplement**

**Earthrise® Spirulina Digest & Flora®: (Capsule)**

**Ingredients:** Earthrise® Spirulina (*Arthrospira platensis*), Fungal/plant-based Digest Enzyme Blend [Protease 1, Protease 2, Protease 3, Lipase, Amylase, Glucoamylase 1, Glucoamylase 2, Lactase, Invertase/Sucrase, Cellulase and Xylanase], Fructooligosaccharides (FOS), Probiotic (*Lactobacillus sporogenes*), Apple Cider Vinegar and Peppermint Leaf (*Mentha piperita*).

**Structure/Function Statements**

-Provides Spirulina, a room temperature-stable probiotic, prebiotics and digestive enzymes to balance digestive system function.\*

-Earthrise® Spirulina Digest & Flora® provides an all-inclusive proprietary formula of Spirulina, a room temperature-stable probiotic (*Lactobacillus sporogenes*), prebiotic fructooligosaccharides (FOS) and 11 digestive enzymes that work in harmony to support gastrointestinal function, antioxidant protection and immunity.\*

-Supports gastrointestinal function, integrity & immunity.\*

\*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.

(The disclaimer appears in the appropriate places on labels and brochures).

**E N D**