

# The Law Office of Holly Bayne, P.C.

Holly J. Bayne, Attorney at Law  
Licensed to Practice in the  
District of Columbia and California

July 20, 2009

## BY FEDERAL EXPRESS

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

## NOTIFICATION OF STATEMENTS OF NUTRITIONAL SUPPORT

This notification is filed by The Law Office of Holly Bayne, P.C., on behalf of Natreon, Inc., 2-D Janine Place, New Brunswick, New Jersey 08901 (Natreon), pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 343(r)(6), and Food and Drug Administration (FDA) regulations at 21 C.F.R. § 101.93.

Name of Dietary Supplement	PrimaVie®
Name of Dietary Ingredient	Shilajit (mineral pitch), as described in U.S. Patent Nos. 6,440,436; 6,558,712; 6,869,612 B2 and 7,250,181 B2.

### Statements of Nutritional Support for the Dietary Supplement

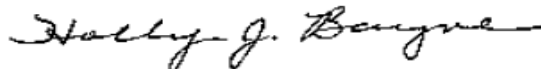
- PrimaVie® works at the cellular level, making it a key contributor to healthy mitochondrial function and energy.
- Working at the cellular level, PrimaVie® plays a direct role in the synthesis of Adenosine triphosphate, or ATP, the primary energy currency in the body
- PrimaVie® has targeted action for increasing energy, revitalizing the body and mind, and supporting the aging process.
- PrimaVie® is an effective rejuvenator to support normal physiological functions.
- PrimaVie® has adaptogenic properties, helping to combat the effects of physical and environmental stress.

601 Pennsylvania Avenue, N.W. • Suite 900 South Building • Washington, D.C. 20004  
Tel (202) 220-3101 • Fax (202) 639-8238  
E-mail Holly@Bayne-Associates.com

- PrimaVie® supports the body during stress.
- As an adaptogen, PrimaVie® helps the body increase resistance to fatigue while providing energy, vitality, and well-being, in part, by augmenting Coenzyme Q-10 activity.
- Modern research has shown that PrimaVie® functions as a transporter or carrier to enhance the bioavailability of other nutrients into the body's cells.
- As an adaptogen, PrimaVie® helps combat non-specific loss of vigor associated with aging.
- Shilajit has been used since ancient times to support male reproductive health.
- Modern research demonstrates PrimaVie® enhances male sexual function and promotes healthy testosterone levels.
- In a clinical study, PrimaVie® was shown to promote healthy sperm production and enhance male reproductive health.
- In a clinical study, PrimaVie® was shown to enhance sperm quality and motility.
- PrimaVie® has been clinically shown to promote healthy semen production and sperm count.
- PrimaVie® helps combat oxidative stress. In a clinical study, subjects taking PrimaVie® were found to have lower semen levels of Malondialdehyde, a naturally-occurring compound that is a marker of oxidative stress.
- PrimaVie® works synergistically with CoQ-10 to promote mitochondrial energy synthesis.
- PrimaVie® has a sparing effect on CoQ-10.
- PrimaVie® protects cellular mitochondria, the energy-producing parts of cells, from oxidative damage caused by free radicals.
- PrimaVie® boosts mitochondrial energy synthesis, an essential biological process for healthy aging.

Pursuant to FDA regulation 21 C.F.R. § 101.93(a)(3), a signed certification is attached to this notice.

Sincerely,



Holly J. Bayne  
Counsel to Natreon

HJB/sr  
Enclosures