



8757
NOV - 9 2003
2003

November 25, 2003

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

To Whom It May Concern:

Notice is hereby given pursuant to the requirements of Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(6)) and in accordance with the requirements of 21 CFR Section 101.93 that Juvenon, Inc. is marketing a dietary supplement containing acetyl-L-carnitine HCl and alpha lipoic acid under the Juvenon Energy Formula brand name. While Juvenon disputes that its website constitutes "labeling" under 21 CFR 101.93, out of an abundance of caution, I note that the following statements of nutritional support appear on the Juvenon website:

- Reduces toxic oxidants / Enhancing anti-oxidative protection / Reducing the level of free radicals / Reduce toxic oxidants & age-associated cell damage
- Promotes healthy cells / Promoting cellular health
- Boosts energy levels / Increasing energy production / Increase natural energy and vitality / Increased energy, spread throughout the day
- Improves metabolic efficiency / Promoting metabolism and cell function / Maintaining optimum metabolic activity
- Maintaining the membrane potential / Maintaining a high membrane potential
- Feel younger
- Delay the effects of cellular aging / Helps delay cellular aging
- Enhanced sense of well-being / Feeling of well-being
- Improved sleep / Improved quality of sleep

21-C Orinda Way #132, Orinda, CA 94563-2510
Tel: (925) 253-8432 / Fax: (925) 253-8436

97S 0162

LET

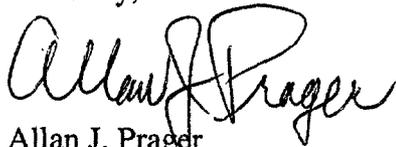
13438

- Greater mental acuity / Greater mental alertness
- Healthy immune response
- Healthy hair and skin
- More self confidence.

I hereby certify that the information contained in this notice is complete and accurate and that Juvenon, Inc. has substantiation that these statements are truthful and not misleading. Juvenon, Inc. is located at 21-C Orinda Way #132, Orinda, CA 94563-2510.

Pursuant to 21 CFR Section 101.93, two copies of this notification are enclosed.

Sincerely,

A handwritten signature in black ink, appearing to read "Allan J. Prager". The signature is written in a cursive, flowing style.

Allan J. Prager
President & CEO
925-253-8432