

# EMORD & ASSOCIATES, P.C.

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July 8, 1997

## VIA UPS NEXT DAY AIR

Elizabeth A. Yetley, Ph.D., R.D.

Director

Office of Special Nutritionals

Food and Drug Administration

Center for Food Safety and Applied Nutrition

200 C Street, S.W., HFS-450

Washington, DC 20204-0001

0220 '97 SEP 19 P1:52

Re: 21 U.S.C. § 343(r)(6) Statement of Nutritional Support Notice

Dear Dr. Yetley:

Pure Encapsulations, Inc., 490 Boston Post Road, Sudbury, MA 01776, by counsel and in accordance with 21 U.S.C. § 343(r)(6) and 61 FR 50771 (Sept. 27, 1996), hereby submits an original and two copies of its notice of intent to use the following statements of nutritional support. The statements will be made in labeling that will accompany the sale of Androstenedione, a dietary supplement in one of two kinds: gelcaps containing 25 mg or containing 50 mg of Androstenedione. Pure retains scientific documentation corroborating its statement.

### Androstenedione

\* Androstenedione, an adrenal androgen, is a naturally occurring hormone found in the body and in some plants. When supplemented, androstenedione has been shown to increase blood levels of both androstenedione and testosterone. At optimal levels, the natural steroid hormone, testosterone, is responsible for enhancing muscle mass and bone tissue, while increasing energy levels and strength, all of which decrease with age.

\* Androstenedione supports and supplements the body's natural bio-synthesis of testosterone, providing for healthy muscle mass and bone tissue, while elevating energy levels.

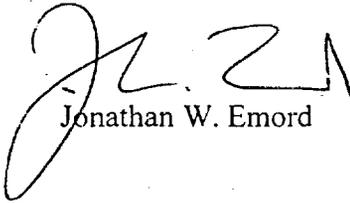
In accordance with 21 U.S.C. § 343(r)(6) each of the above statements will be followed by an asterisk that will be cross-referenced to another asterisk next to which will

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appear the following statement in bold-faced type: **“This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”**

Respectfully submitted,



Jonathan W. Emord

Attachments