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September 9, 1996

**VIA HAND DELIVERY**

The Hon. Donna E. Shalala

Secretary

Department of Health and Human Services

Sixth Floor

200 Independence Avenue, S.W.

Washington, D.C. 20201

Re: Fulfillment of Reporting Obligation  
under 21 U.S.C. § 343(r)

Dear Secretary Shalala:

Trace Minerals Research, by counsel and in accordance with the requirements of 21 U.S.C. § 343(r), hereby reports its statements of nutritional support. Under that section, companies are not only required to make such a reporting but also to retain substantiation for each such statement. In proof of its compliance with that additional requirement, Trace Minerals Research herein provides a representative sampling of some, but not all, of the scientific references it retains in support of the statements. In accordance with the requirements of Section 343(r), Trace Minerals Research includes the following disclaimer in boldface type, prominently displayed upon each piece of literature that bears any statement listed below: **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.**

<u>Product</u>	<u>Statement</u>	<u>Representative Sampling of Supportive Data</u>
PriMale Energy	These herbs have been used to maintain a man's body function in its prime throughout his lifetime.	<u>Siberian Ginseng</u> , Duke, James, Dr., <i>Handbook of Medicinal Herbs</i> , CRC Press 1985, Pg. 174. <u>Damiana</u> , Duke, James, Dr., <i>Handbook of Medicinal Herbs</i> , CRC Press 1985, Pg. 492.

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Sarsaparilla, Holmes, Peter, *The Energetics of Western Herbs*, Artemis Press 1989, Pg. 601.

Gotu Kola, Duke, James, Dr., *Handbook of Medicinal Herbs*, CRC Press 1985, Pg. 110.

Saw Palmetto, Duke, James, Dr., *Handbook of Medicinal Herbs*, CRC Press 1985, Pg. 443.

Capsicum, Duke, James, Dr., *Handbook of Medicinal Herbs*, CRC Press 1985, Pg. 98.

PriMale Energy provides subtle benefits for men, as well as dramatic improvements to men's sexual health.

Zinc, *The American Medical Association Encyclopedia of Medicine*, RandomHouse 1989, Pg. 1087.

Zinc, Schauss, Alexander, G., *Minerals and Health*, Life Sciences Press 1985, Pgs.12-13.

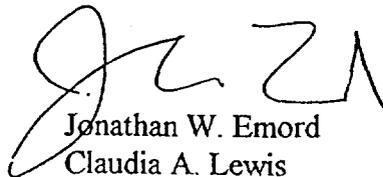
Saw Palmetto, *Research Reviews: Saw Palmetto Extract in the Treatment of BPH*, Herbal Gram, 34, Pg. 12.

PriMale Energy is specifically formulated to give increased energy and vitality.

Ginseng, *British Herbal Compendium*, The British Herbal Medicine Association, 1992, Pg. 90.

Gotu Kola, Yaychuk, Irene, *The Study of Mandookaparni and Punarnava for their Pasaayan Effect on Normal Healthy Adults*, July 1969, Pg. 41.

Respectfully submitted,



Jonathan W. Emord  
Claudia A. Lewis