Proprietary Wellness, LLC
March 23th, 2009

Dr. Susan Walker, Ph.D.
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W. (HFS-450)
Washington, DC 20204

Dear Dr. Walker,
Pursuant to Section 8 of the Dietary Supplement Health and Education Act of 1994, Proprietary Wellness, LLC, Silver Springs, Nevada on behalf of its licensees, wishes to notify the Food and Drug Administration that it will market a new dietary ingredient, 4-dehydroepiandrosterone, a dietary ingredient on the market prior to October 15, 1994. Accordingly, enclosed please find two (2) copies of this notification.

The dietary supplement that contains 4-dehydroepiandrosterone will consist of twenty five (25) milligrams of 4-dehydroepiandrosterone in a tablet or capsule that will be suggested to be taken up to three times per day.

Attached please find a summary and references which establish that this dietary ingredient, when used under the conditions suggested in the labeling of the dietary supplement, is reasonably expected to be safe.

Section 1

a) Proprietary Wellness
PO Box 3540
2840 Highway 95
Alt. S. #7
Silver Springs, Nevada 89429

b) Carolyn Morrison – Resident Agent

Section 2

a) The name of the dietary ingredient is 4-dehydroepiandrosterone.

Section 3

a) The dietary supplement that contains 4-dehydroepiandrosterone will consist of twenty five (25) milligrams of 4-dehydroepiandrosterone in a tablet or capsule that will be suggested to be taken up to three times per day.

b) The label will contain the following instructions for use: "DIRECTIONS FOR USE: This product is for male adults over the age of 21 only. Do not exceed recommended dosage. This product is not intended to diagnose, treat, cure, or prevent any disease." KEEP OUT OF REACH OF CHILDREN – NOT SUITABLE FOR PREGNANT OR LACTATING WOMEN.

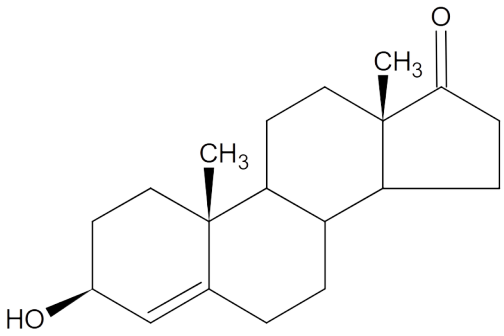
Section 4

4.1 *Background:*

To make dietary supplements compliant under current DSHEA regulation, a supplement must be naturally occurring and part of the food supply where the food has not been chemically altered. The endogenous formation of androstenedione has been well documented in healthy human and animal tissues. Under DSHEA, 4-DHEA is a natural metabolite of androstenedione and DHEA that is proven to occur in rabbits, sheep and rats(1,2). Rabbit and sheep flesh and organ tissue has been consumed by humans since antiquity. This ingredient, though standardized has not been chemically altered from the animal tissues where it is found.

The CAS number for this compound is not available.

4.1.1 *Structure:*



4.2 *Name of Ingredient:*
Androst-4-ene-3-ol-17-one (4-dehydroepiandrosterone)

4.2.1 *Manufacturing Process:*
Products will be manufactured in a variety of cGMP certified facilities.

4.2.2 *Product Specifications:*

a) Dry white powder, >95% purity.
* Proprietary Wellness LLC is not: a raw material manufacturer, copacker, nor commercial brand. It is expected that each manufacturer will provide their own specifications.
* Proprietary Wellness LLC expects the ingredient to be manufactured at greater than 98% purity to be covered under this NDI, thus making the ingredient "pure" by manufacturing standards."

b) HPLC, FTIR, GCMS

4.3.1 *Safety of Ingredient:*
DHEA has a long history of use in healthy and diseased humans (4,5,6,8) and has been shown to be safe in doses up to 200 mg per day for 24 weeks (9) and 2250 mg for 16 weeks (7) with minimal side effects. The side effects that are encountered are due, in large part to the formation of estrogen and potent 5-alpha reduced metabolites (3,9,10). DHEA has been shown to act as a direct agonist of the estrogen receptor while there is no evidence that 4-DHEA has this activity. Numerous opinions have been written showing that comparing an ingredient to one that is already on the market is a valid and defensible form of showing safety. The numerous benefits of 4-DHEA over standard 5-DHEA make this certainly more safe and effective as a means of increasing adrenal hormones.

Dose Considerations:
The appropriate dose of 4-dehydroepiandrosterone for human consumption was determined from reference to well-tolerated doses of DHEA, a similar adrenal hormone. Based upon the rationale that 4-dehydroepiandrosterone has a similar level of safety in comparison to DHEA (10), clinical studies have been found showing that the use of up to 200 milligrams per day for 6 months is both safe and well-tolerated by humans (10). Additionally, the compound is currently on sale as a dietary supplement and is in the food

supply at 4-8 times our recommended dose. Therefore, we conclude that this compound is safe when used as intended.

4.3.2 *Regulatory Status:*
4-dehydroepiandrosterone is not a drug, nor has it ever been marketed as such in the United States.

4.3.3 *Pharmacokinetics:*
The compound and its direct isomers are well known and well studied in humans and other mammals (1-16).

4.3.4 *Toxicity:*
We do not know of references for toxicity data other than the reported history of safe use.

4.3.5 *Clinical Data:*
We do not know of clinical references for this compound.

Section 5

4-dehydroepiandrosterone is present in the food supply and has been adequately shown through experience based on "common use in food" to be "safe" for use as a dietary supplement.

References

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3. Longcope C, Bourget C, Flood C. The production and aromatization of dehydroepiandrosterone in post-menopausal women. Maturitas. Dec;4(4):325-32, 1982

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10. Acacio BD, Stanczyk FZ, Mullin P, Saadat P, Jafarian N, Sokol RZ. Pharmacokinetics of dehydroepiandrosterone and its metabolites after long-term daily oral administration to healthy young men. Fertil Steril. Mar;81(3):595-604, 2004