

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, nordehydroepiandrosterone, 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 nordehydroepiandrosterone will consist of twenty five (25) milligrams of nordehydroepiandrosterone 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 nordehydroepiandrosterone.

Section 3

- a) The dietary supplement that contains nordehydroepiandrosterone will consist of twenty five (25) milligrams of nordehydroepiandrosterone 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:*

Dehydroepiandrosterone (DHEA) is a dietary ingredient that was marketed in the United States before October 15, 1994. DHEA.

The endogenous formation of norandrostanes has been well documented with norandrosterone, norepiandrosterone, noretiocholanolone detected in healthy human and animal tissues (7,8,9,10,11,12,13). The formation of 19-nor-metabolites has been suggested to be a byproduct of the incomplete aromatization of androgens to estrogens (12). DHEA is known to undergo aromatization to estrogens (1) therefore it is also subject to conversion to 19Nordehydroepiandrosterone.

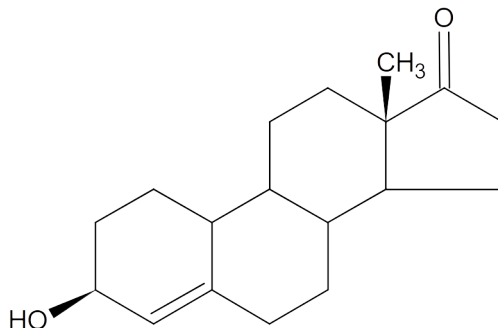
The presence of endogenous norandrostane metabolites in urine and tissues strongly suggests the formation of 19-norDHEA through the incomplete action of aromatase in vivo.

19-norandrostanes are also NATURALLY present in the food chain (8,11,13). Consumption of a meal consisting of boar meat or testes resulted in high plasma levels of both norandrosterone and noretiocholanolone (8). Boar meat and testes contain high

levels of norandrostenedione which has been shown in the literature to also convert into 19NorDHEA and when consumed has been shown to result in the excretion of 19-norDHEA in human urine (22).

The CAS number for this compound is not available.

4.1.1 *Structure:*



4.2 *Name of Ingredient:*

Estr-4-ene-3-ol-17-one (nordehydroepiandrosterone)

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 and has been shown to be safe in doses up to 200 mg per day for 24 weeks (20) and 2250 mg for 16 weeks (18) 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 (4,20,21). DHEA has been shown in the literature to convert via the aromatase enzyme to estrogens (1). In addition, DHEA has been shown to convert to more potent 5-alpha reduced metabolites. 19-norandrostanes, including 19-norDHEA, are known to convert to less potent metabolites through 5-alpha reduction. In addition, the lack of a carbon in the 19-position

reduces affinity for the aromatase enzyme and results in reduce aromatization to estrogens (14,15). 19-norDHEA would therefore be expected to have a better safety profile than DHEA. 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 19NorDHEA over standard 5-DHEA make this certainly more safe and effective as a means of increasing adrenal hormones.

Dose Considerations:

The appropriate dose of nordehydroepiandrosterone for human consumption was determined from reference to well-tolerated doses of DHEA, a similar adrenal hormone. Based upon the rationale that nordehydroepiandrosterone has a similar level of safety in comparison to DHEA (21), 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 (21). 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:*

nordehydroepiandrosterone 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

nordehydroepiandrosterone 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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