

Oral Delivery Technologies  
37 Prospect Street  
Nutley, NJ  
07110

December 28<sup>th</sup>, 2005

Division of Standards and Labeling Regulations  
Office of Nutritional Products, Labeling and Dietary Supplements(HFS-820)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park Md.  
20740-3835

Dear Sirs,

Pursuant to Section 8 of the Dietary Supplement Health and Education Act of 1994, on behalf of Oral Delivery Technologies (ODT) on its own behalf and on behalf of Netrients.com, wishes to notify the Food and Drug Administration that it will market a new dietary supplement consisting of a combination of 2.5mg of androsta 1,4,6 triene 3,17 dione, an endogenous C19 compound (as shown in Brueggemeier Sex Hormones :Analogues and Antagonists Chapter 3 Table 3) and 2.5 mg of 17hydroxy 6methylene androsta 1,4 diene, 3-one within a fast dissolve citrus flavoured tablet. The tablet is to be consumed singly or double dose twice daily for a maximum daily consumption of 20mg of the active ingredient. The first compound, a "suicide type" aromatase inhibitor has been shown to be safe in larger daily intake in combination with other anti-aromatase inhibitors (see attachment Effects of Two Naturally Occurring Aromatase Inhibitors on Male Hormonal and Blood Chemistry profiles Trimmer, Johnson June 2005). The dosage was three capsules containing a total of 75mg of the anti-aromatase androsta 1,4,6 triene 3,17 dione and 75mg of the anti-aromatase 3-OHAT ether. Blood profiles after 28 days of consumption and a further 28 days after cessation of consumption showed no adverse effects on blood chemistry profiles. The second compound is a derivative of the endogenous compound 17hydroxy progesterone. The endogenous enzyme 17 alpha hydroxylase/17,20 lyase cytochrome P450 changes the C21 to a C19 compound. Dehydrogenation occurs at the 1 position and methylation and dehydrogenation occur at the 6 position. As can be seen in Brueggemeier Chapter 3 Endogenous Male Sex Hormones Table 3 substitution at the 6 position does occur naturally.

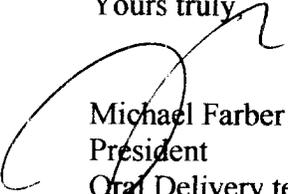
Attached please find a summary and reports of safety studies and other information with respect to all the major ingredients in the above mentioned dietary supplement.

1. Excerpts from Brueggemeier Sex Hormones (Male): Analogues and Antagonists

2. Study by Trimmer and Johnson Effects of Two Naturally Occurring Aromatase Inhibitors on Male Hormonal and Blood Chemistry Profiles
3. Review of companies currently marketing comparable products (Legal Gear..1 Methyl P....17 hydroxy progesterone derivative with 6 methyl ethyl attachment)
4. The appropriate cautionary warnings with regard to potential interactions, not for use by persons with elevated blood pressure, cardiovascular disease or suspected disease or history, not for use by persons with prostate disorders or history of disorder or suspected disorders of the prostate, persons taking MAO inhibitors and other possible drug interactions, not for use by persons under age 21, not for use by women, not for use by pregnant women or lactating women, not for use by persons with diagnosed or suspected behavioural disorders, always consult a physician before commencing any diet or supplement or exercise program, along with specific limitations as to use and the required mandatory statements for dietary supplements from the FDA will be clearly shown on all labeling and advertisements.

Should there be any questions with respect to this filing please do not hesitate to contact the undersigned.

Yours truly,



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