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## Notification of Marketing of a Dietary Supplement Bearing Statements Listed in Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act.

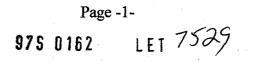
**TO:** Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition, Food and Drug Administration 200 c St. SW., Washington, D.C. 20204

## FROM:PatentHEALTH, LLCJohn A. Armstrong, Staff Counsel & Press Secretary<br/>7800 Whipple, Ave. N.W.,<br/>N. Canton, Ohio 44720<br/>(330) 494-5504 ext. 872

**DATE:** March 20,200 1

In accordance with Title 2 1, Section 10 1.93 of the Code of Federal Regulations, I submit to your Office the following information as required for our notification of marketing of a dietary supplement bearing statements listed in Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act.

- 1. As the <u>distributor</u> of the dietary supplement that bears statement(s) listed in Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, our name and address is:
  - a. PatentHEALTH, LLC 7800 Whipple Ave. N.W., N. Canton, Ohio 44720
- 2. The text of the statements being made upon our dietary supplement label and display box are attached hereto as "Appendix 1."
- 3. The name of the dietary ingredient that is the subject of the statement is: **3-Acetyl-7-Oxo-Dehydroepiandrosterone.**



4. The name of the dietary supplement upon whose label the statement appears is: **PatentLEANTM**.

5. I, John A. Armstrong, Staff Counsel and Press Secretary of PatentHEALTH, LLC, located at 7800 Whipple Ave. N. W., N. Canton, Ohio 44720, certify that the information presented within this notice is complete and accurate, and that the **notifying** firm has substantiation, consisting of competent and reliable scientific evidence, that the statements therein are truthful and not misleading.

(Signature)

## Appendix 1

• Effective and Trusted Fat and Weight Loss

2.

- Shown to be effective for promoting weight loss over 8 weeks in **clinical** tests when used as directed.
- with a calorie restricted diet and regular exercise, **PatentLEAN** optimizes loss of body fat.
- **PatentLEAN's** active ingredient **(3-Acetyl-7-Oxo** Dehydroepiandrosterone) is an Effective and Trusted Dietary supplement derived from all natural sources
- Awarded United States Patent for Weight Loss
- Awarded United States Patent number **5,296,481** for promoting weight loss.
- **PatentLEAN** was awarded and is Protected by United States Patent **#5,296,481** for Weight Loss
- **PatentLEAN,** proper caloric consumption and exercise are recognized for effective weight loss