Department of Health and Human Services

Public Health Service
Food and Drug Administration
Center for Food Safety and
Applied Nutrition
Office of Compliance
5100 Paint Branch Pkwy
College Park, MD 20740

March 8, 2006
WARNING LETTER
VIA FACSIMILE

Legal Gear
815 N 2nd St #109
Brighton, MI 48116

Dear Sir or Madam:

This letter relates to your product Legal Gear Methyl 1-P®, containing the synthetic steroids 6-alpha-methyl-etiocholene-3,17-dione and 17a-hydroxyprogesterone. The product label and your Internet website at www.legalgear.com list 6-alpha-methyl-etiocholene-3,17-dione as an ingredient, and analysis of this product revealed that it is also contains another steroid not declared as an ingredient, 17a-hydroxyprogesterone. The product label and your website state that this product contains an "anabolic agent." Further, your website includes statements about this product such as the following:

- "[E]ven more potent at building muscle than many illegal anabolics!"
- "[T]he only legal choice for people wanting to build serious mass and gain massive strength"

The product label and your website represent this product as a dietary supplement. However, the product cannot be a dietary supplement because the active ingredients used in the product, 6-alpha-methyl-etiocholene-3, 17-dione and 17a-hydroxyprogesterone, are not vitamins, minerals, amino acids, herbs, or other botanicals, or dietary substances for use by man to supplement the diet by increasing the total dietary intake, nor are they concentrates, metabolites, constituents, extracts, or combinations of any dietary ingredient described above. Rather, both of these ingredients are synthetic steroids. Consequently, 6-alpha-methyl-etiocholene-3,17-dione and 17a-hydroxyprogesterone are not "dietary ingredients" as defined in Section 201(ff)(1) of the Federal Food, Drug and Cosmetic Act (the Act) [21 USC 321(ff)(1)],and your product is not a dietary supplement because it does not contain a dietary ingredient.

Under Section 201(g)(1) of the Act [21 USC 321(g)(1)(C)], products that are intended to affect the structure or function of the body are defined as drugs. The description of your product as "anabolic" on your product label and website, together with the other claims quoted above, establish that your product is intended to affect the structure or function of

the body by building muscle and increasing strength. Based on these claims, FDA considers Legal Gear Methyl 1-P® to be a drug.

Moreover, your product is also a new drug under Section 201(p) of the Act [21 USC 321(p)] because this product is not generally recognized as safe and effective for the uses claimed in its labeling. Under Section 505(a) of the Act [21 USC 355(a)], a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved new drug application (NDA) is in effect for it. Because your product is not the subject of an approved NDA, it may not be marketed in the United States and its continued distribution violates Section 505(a) of the Act. Section 301(d) of the Act [21 USC 331(d)] prohibits the introduction or delivery for introduction into interstate commerce of any article in violation of Section 505.

You should also be aware that anabolic steroids may cause serious long-term adverse health consequences in men, women, and children. These include liver toxicity, testicular atrophy and male infertility, masculinization of women, breast enlargement in males, short stature in children, adverse effects on blood lipid levels, and a potential to increase the risk of heart attack and stroke.

The violations of the Act described above are not intended to be an all-inclusive list of violations concerning your firm and its products. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

We request that you take prompt action to correct these violations and any similar violations associated with other other products you market that contain 6-alpha-methyl-etiocholene-3, 17-dione or 17a-hydroxyprogesterone. Failure to promptly correct the violations may result in FDA enforcement action without further action. The Act provides for seizure of illegal products, injunction against the manufacturers and distributors of illegal products, and criminal sanctions against persons responsible for causing violations of the Act [21 USC 332, 333, and 341].

Please notify this office in writing, within fifteen working days of receipt of this letter, as to the specific steps you have taken to correct the violations described above, and an explanation of each step taken to assure that similar violations will not recur. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be implemented. In your reply, please describe your intent with respect to products that have already been distributed.

Your reply should be sent to the attention of Jennifer Thomas, Compliance Officer, US Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Compliance (HFS-607), 5100 Paint Branch Pkwy, College Park, MD 20740.

Sincerely,
/s/
Joseph R. Baca
Office Director