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VIA FEDERAL EXPRESS

Our Reference: 2950821

November 30, 2000

Robert M. Walls, CEO/President
SportPharma USA, Inc.
1915 Mark Court, #150
Concord, CA 94520

Dear Mr. Walls:

WARNING LETTER

The U.S. Food and Drug Administration (FDA) has reviewed the labels of the following dietary supplements that are marketed under the brand name, SportPharma USA. Investigator Joan T. Briones collected samples and labels of the dietary supplements during her inspection of your firm on March 27 and 31, 2000. Investigator Briones sampled three dietary supplements for FDA laboratory analyses, which are flagged by an asterisk in the following tabulation:

Dietary Supplements

Actisyn, Active Protein Synthesizer*
Multigard, Advanced Anti-Oxidant Formula*
Promax, Muscle Building Protein*
Vanadyl, Potent Insulin Mimicker
L-Carnitine, Natural Fat Burner
Creatine, Pure Micronized Creatine Monohydrate
Pyruvex, Boost Energy—Fight Fat
Thyroburn, Stimulant Free
Creavol ATP, Maximum Performance
Cyclone, Prohormone Stack
Thermodrene, Thermogenic Stimulator
Ribose, Cellular Energy Source

FDA review of the label for the product, Cyclone, reveals that it is in violation of the drug provisions of the Federal Food, Drug, and Cosmetic Act (the Act). This product is promoted as a dietary supplement for sublingual administration with directions to "place

two sublingual tablets under the tongue and let dissolve completely...tablets should not be swallowed..." Because only orally ingested products are considered to be dietary supplements, this product is not eligible for marketing as a "dietary supplement." Furthermore, based on the labeled claim for this product and its intended use ("...maximize gains in lean muscle mass"), the product is a drug [section 201(g)(1)(C) of the Act because it is a product (other than a food) intended to affect the structure/function of the body. It is also a new drug [section 201(p) of the Act] and may not be legally marketed in the United States without an approved New Drug Application [section 505(a) of the Act]. The drug is also misbranded because the labeling fails to bear adequate directions for use [section 502(f)(1) of the Act] and is false and misleading as it suggests that the product is safe and effective for the intended uses when this has not been established [section 502(a) of the Act].

FDA review and analysis reveals that the labels cause the above remaining products to be in violation of section 403 of the Act and Title 21, Code of Federal Regulations, Part 101 (21 CFR 101)—Food Labeling, as follows:

The dietary supplement products are misbranded within the meaning of sections 403(i)(1) and 403(s)(2)(B) of the Act in that the labels fail to identify the products using the term dietary supplement (21 CFR 101.3(g)). Although the term dietary supplement is declared in the label for Creavol ATP, it is not as prominent and conspicuous as Creavol ATP, and its placement is so far removed from Creavol ATP that it can easily be misinterpreted as not part of the product identity (21 CFR 101.3(d)).

The products, Actisyn, Multigard, Promax, L-Carnitine, Pyruvex, and Creavol ATP, are misbranded within the meaning of section 403(q)(5)(F) of the Act in that the labels fail to bear nutrition labeling (Supplement Facts panel), which is required under 21 CFR 101.36, and are not exempt from this requirement.

The statement, "Manufactured by FDA-registered manufacturer to meet FDA guidelines," declared on the label for the product, Creatine, is false and misleading within the meaning of section 403(a)(1) of the Act in that FDA has no system in place for the registration of dietary supplement manufacturers and has not promulgated guidelines for dietary supplements or their manufacture.

The product, Pyruvate, is misbranded within the meaning of section 403(i)(2) of the Act in that the label fails to declare the common or usual name of the ingredient, ChromeMate, which is a registered trademark designation (21 CFR 101.4).

The Muscle Building Protein Promax product is misbranded within the meaning of 403(s)(2)(E)(ii)(I) of the Act in that the product fails to have the strength that it is represented to have with respect to Vitamin C. FDA laboratory analysis found only 28.5% of the labeled quantity of 110% of the daily value for Vitamin C, per 67 grams (2 scoops) of product (21 CFR 101.36(b)).

We note that the labels for the products, Multigard, Vanadyl, L-Carnitine, Creatine, and Termodrene, bear claims that appear to be claims described under section 403(r)(6) of the Act but do not include the mandatory disclaimer required by section 403(r)(6) of the Act and 21 CFR 101.93(b)-(e). Your firm also has not submitted the notification required by the Act and 21 CFR 101.93(a). Therefore, the products that are the subject of the claims have not claimed the exemption provided for by the Act for dietary supplements, and they may be subject to regulation as drugs under section 201(g)(1)(C) of the Act.

The requirement that the disclaimer be used and the failure to use it causes a product to be a drug under 201(g)(1)(C) of the Act is discussed in detail in the preamble to the January 6, 2000 final rule on structure/function claims (Federal Register, Volume 65, page 1000 (65 FR 1000); discussion for comment 1 under the Legal Authority section on page 1033). If a firm uses structure/function claims for these products, they must include the disclaimer on each label panel that bears a claim in accordance with 21 CFR 101.93. However, FDA is currently exercising discretion in enforcing this requirement. Small businesses have until July 7, 2001 to comply, and other businesses until January 7, 2001 to comply (see the implementation plan discussion in the January 6, 2000 Federal Register, 65 FR 1000 at 1045). Your firm should be aware that if you make claims for your products and do not adhere to the requirements in 21 CFR 101.93 and section 403(r)(6) of the Act, your products may be subject to regulation as drugs.

Most of the above violations concern certain new labeling requirements. The above violations are not meant to be an all-inclusive list of deficiencies on your labels. Other label violations can subject the dietary supplements to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes and regulations enforced by FDA.

You should take prompt measures to correct the violations. Failure to promptly correct these violations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 days, state the reasons for the delay and the time at which the corrections will be completed.

Your reply should be directed to Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions concerning the violations noted, then please contact Ms. Kishida at (510) 337-6824.

Sincerely,



Steven R. Gillenwater
Acting District Director

cc: Darren H. Wardle, General Manager
SportPharma USA, Inc.
1915 Mark Court, #150
Concord, CA 94520