



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

g1593d

San Francisco District  
1431 Harbor Bay Parkway  
Alameda, CA 94502-7070  
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

Our Reference: 2954888

August 2, 2001

Gregory A. Pickett, President  
GMP Manufacturing, Inc.  
1910 Mark Court, Suite 130  
Concord, CA 94520

**WARNING LETTER**

Dear Mr. Pickett:

We inspected your firm, located at 1910 Mark Court, Suite 130, Concord, California on January 10, 11, and 17, 2001 and found that you have serious violations of Section 403 of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the food and dietary supplement labeling regulations through links in the Food and Drug Administration's (FDA's) home page at [www.fda.gov](http://www.fda.gov).

The product ProPower is misbranded under Section 403(q)(1) because it does not bear nutrition labeling in accordance with Title 21, Code of Federal Regulations, Part 101.9 (21 CFR 101.9). Although labeled as a dietary supplement, this product is a conventional food and not a dietary supplement because it is represented as a "nutritionally complete high-protein meal," and a dietary supplement does not include a product that is "represented for use as a conventional food or as a sole item of a meal or the diet. (Section 201(ff)(2)(B) of the Act)

The products, Complete Gainer Power, Complete Whey Power, ProPower, Cytomax Exercise and Recovery Drink (Peachy Keen, Cool Citrus, and Apple Berry Flavors), and Cytomax Lite (Lemon Iced Tea Flavor) are misbranded because they contain artificial flavors but are not labeled "artificial" or "artificially flavored." If a food contains any artificial flavor which simulates, resembles or reinforces a characterizing flavor, then the characterizing flavor shall be accompanied by the word(s) "artificial" or "artificially flavored." [Section 403(k) of the Act and 21 CFR 101.22(i)(2)]

The products Cytomax Exercise and Recovery Drink (Peachy Keen, Cool Citrus, and Apple Berry flavors) and Cytomax Lite (Lemon Iced Tea Flavor) contain a "Supplement Facts" panel. However, the product labels do not identify the products as dietary supplements. If these products are intended to be dietary supplements and not

conventional foods, then they must, among other things, be labeled as such in accordance with Sections 201(ff)(2)(C) and 403(q)(5)(F) of the Act and 21 CFR 101.3(g) and 21 CFR 101.36.

The products, Cytomax Exercise and Recovery Drink (Peachy Keen flavor) and Cytomax Lite (Lemon Iced Tea Flavor) are misbranded because they contain colors but are labeled using the term “no artificial colors.” Where a food substance such as beet juice is deliberately used as a color, as in pink lemonade, it is a color additive and may be declared as “Artificial Color,” “Artificial Color Added,” “Color Added,” or an equally informative term that makes clear that a color additive has been used in the food. [Section 403(k) of the Act and 21 CFR 101.22(k)]

The products, Complete Gainer Power, Complete Whey Power, and ProPower are misbranded because the labels bear one or more of the statements, “low lactose,” “low in lactose,” “containing L-glutamine, taurine, fat burners and lipotrophics,” or “with Herbal Lift!” These statements are unapproved nutrient content claims in that they are made for substances for which no Reference Daily Intakes (RDI’s) or Daily Reference Values (DRV’s) have been established. [Section 403(r)(1)(A) of the Act and 21 CFR 101.13]

The product, Cytomax Exercise and Recovery Drink (Peachy Keen Flavor) is misbranded because the label bears the claim “With anti-oxidants,” which is an approved nutrient content claim, but the claim made for the product is not made in accordance with the regulation. [Section 403(r)(1)(A) of the Act and 21 CFR 101.54(g)]

The products, Complete Gainer Power and Complete Whey Power, are misbranded because the supplement facts labels do not meet several requirements of the Act or regulations. These violations include the fact that some nutrition information (e.g., the declaration of amounts of amino acids) is declared outside of the supplement facts box, some nutrition information (e.g., calories and carbohydrates) is not presented using the increments required by regulation (e.g., calories and carbohydrates), and nutrition information is given that is prohibited by regulation because the dietary ingredients are present in amounts that may be declared “zero” (e.g., dietary fiber for the product Complete Whey Power. [Section 403(q)(5)(F) of the Act and 21 CFR 101.36]

Several products are misbranded because they use terms (in the ingredient list) to describe ingredients that are not a part of the common or usual name of the respective ingredients. These terms include “Special ultrafiltered, non-denatured, ultra high quality” and “special ultrafiltered, non-denatured, high quality” for whey protein concentrate and “pre-digested, ion-exchange” for whey protein hydrolysate (Complete Gainer Power and Complete Whey Power), “ion-exchange” for whey protein isolate (Complete ProPower), “Cytosport’s unique complex carbohydrate blend” and “from corn hybrids” for amylopectin starches and maltodextrins and “Alpha-L-Polylactate™” and “our patented non-acidic L-lactate ionically bound to L-arginine, fructose, glycine, L-histidine and L-alanine, sodium L-lactate, potassium L-lactate, L-pyruvate) for L-lactate (Cytomax (Peachy Keen, Apple Berry, and Cool Citrus flavors), and “CytoCarb Lite™” and “Cytosport’s unique low-glycemic indexed combination of pure crystalline fructose and

complex carbohydrate blend, including amylopectin starches and branching, short, medium and long linear chain maltodextrins with very low "DE" (Dextrose Equivalence)) for maltodextrins (Cytomax Lite LGI) and Ctyd. [Section 403(i)(2) of the Act and 21 CFR 101.4]

This letter is not intended to be an all-inclusive list of deficiencies in your labeling. We note numerous other labeling violations that we have not included in this letter. It is your responsibility to ensure adherence to each requirement of the Act and regulations. You should review all of the labels of your products to assure that they comply with the Act and regulations.

You should know these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to seizure, and/or obtaining a court injunction against further marketing of your dietary supplement products. If you do not correct these violations, we may not provide certificates to your firm for export of your products to European Union (EU) countries.

Please advise FDA in writing, within fifteen (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 response should be directed to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070.

Sincerely,



Dennis K. Linsley  
District Director  
San Francisco District

cc: [REDACTED] CEO

