

to fourfold excess risk of coronary heart disease. Diabetics also suffer from abnormal platelet function, specifically, platelet aggregation, which leads to atherosclerosis and vascular thrombosis, precursors of cardiovascular disease and premature death (American Diabetes Association, *Diab. Care*, (23): 1772–1773 (2000)). Early incorporation of the food ingredients contained in the preferred embodiment of the invention may delay the need for lipid-lowering and anti-platelet-aggregating drugs.

The nutritional supplement can provide benefits to HIV-infected individuals with lipodystrophy. The metabolic changes associated with lipodystrophy can be minimized, reduced and/or prevented by administration of the nutritional supplement of this invention. The metabolic changes are similar to those seen in diabetics, namely insulin resistance, abnormal lipid and trygliceride levels, glucose intolerance accelerated atherosclerosis and enhanced cardiovascular risks. Thus, the benefits of the invention to diabetics can be applicable to individuals with lipodystrophy. Further, control of these metabolic changes may reduce, minimize or prevent the body composition changes (e.g., fat accumulation, fat redistribution) typically associated with lipodystrophy. HIV-infected individuals on antiretroviral therapy (HAART), particularly those receiving protease inhibitors, should benefit from the nutritional supplement as these therapies are thought to be a cause of lipodystrophy. Diet and exercise coupled with the use of the nutritional supplement of the invention should provide a therapeutic regimen to reduce the risks associated with lipodystrophy.

The composition and nutritional supplements of the invention are intended to be orally administered daily. Based on the serving size of 10–15 g powder in 8 oz. water, the recommended dosage is twice daily. For example, if the supplement is in the form of a beverage or food bar, then the patient would consume one after or during each of the two largest meals, where the greatest amounts of fats and cholesterol are likely to be consumed. The recommended daily amounts of each ingredient, as described above, serve as a guideline for formulating the nutritional supplements of this invention. The actual amount of each ingredient per unit dosage will depend upon the number of units daily administered to the individual in need thereof. This is a matter of product design and is well within the skill of the nutritional supplement formulator.

The ingredients can be administered in a single formulation or they can be separately administered. For example, it may be desirable to administer the bitter tasting ingredients in a form that masks their taste (e.g., capsule or pill form) rather than incorporating them into the nutritional composition itself (e.g., powder or bar). Thus, the invention also provides a pharmaceutical pack or kit comprising one or more containers filled with one or more of the ingredients of the nutritional compositions of the invention (e.g., nutritional supplement in the form of a powder and capsules containing herbs and aspirin). Optionally associated with such container(s) can be a notice in the form prescribed by a government agency regulating the manufacture, use or sale of pharmaceutical products, which notice reflects approval by the agency of manufacture, use of sale for human administration. The pack or kit can be labeled with information regarding mode of administration, sequence of administration (e.g., separately, sequentially or concurrently), or the like. The pack or kit may also include means for reminding the patient to take the therapy. The pack or kit can be a single unit dosage of the combination therapy or it can be a plurality of unit dosages. In particular, the agents can be separated, mixed together in any

combination, present in a formulation or tablet. Agents assembled in a blister pack or other dispensing means is preferred.

All references provided cited are incorporated by reference in their entirety.

EXAMPLE

Recipe for a Nutritional Supplement for Patients with Type 2 Diabetes Mellitus

In one embodiment, the nutritional supplement is a beverage that provides 45 kcal/unit serving, where one unit serving is a 11 gram powder in 8 oz. of water, and is to be administered twice daily. The invention has the following characteristics:

approximately 7 g carbohydrate: fructose (2 g), konjac flour (1 g) (from Opta Food Ingredients, Bedford, Mass.), psyllium (1 g), 2 g other sources (e.g., whey, lecithin, willow bark, flavors, colors) barley (1 g); aspartame to sweeten;

approximately 2 g protein: preferably, whey protein concentrate. Soy, casein, or other high biological value proteins may be substituted to improve flavor;

approximately 1.5 g fat: as 1 g canola oil and 0.5 g other (e.g., lecithin, whey);

approximately 1.6 g plant component: mixture of lecithin and of plant sterol (lowers total and LDL-C) as a lecithin micelle;

approximately 100 μ g chromium: as picolinate (from AMBI/Nutrition 21);

approximately 267 mg willow bark: (Net Chem, Seattle, Wash., 15% concentrate or active compound); and

approximately 100 mg ginseng (Gerimax, Ginseng Extract, (GGE) Dansk Droge A/S, Denmark).

While this invention has been particularly shown and described with references to preferred embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the scope of the invention encompassed by the appended claims.

What is claimed is:

1. A nutritional supplement, comprising a low-glycemic index carbohydrate source, a source of protein, a source of fat, a source of sterol and/or stanol, a source of chromium, a source of salicylic acid, and a source of ginseng.

2. The nutritional supplement of claim 1, wherein the nutritional supplement is in the form of a powder.

3. The nutritional supplement of claim 1, wherein the nutritional supplement is in the form of an extruded bar.

4. The nutritional supplement of claim 1, wherein the carbohydrate source further provides a source of fiber.

5. The nutritional supplement of claim 3, wherein the carbohydrate source comprises barley flakes, konjac mannan, fructose or combination thereof.

6. The nutritional supplement of claim 4, wherein the carbohydrate source is psyllium.

7. The nutritional supplement of claim 1, wherein the protein source is of a high biological value.

8. The nutritional supplement of claim 6, wherein the protein source comprises at least one protein source selected from the group consisting of whey, casein, soy, milk, egg and combination thereof.

9. The nutritional supplement of claim 1, wherein the fat source is a nonatherogenic oil.

10. The nutritional supplement of claim 9, wherein the nonatherogenic oil is a vegetable oil.