NNC JR 7-9-90

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Atlanta Field Office

-01

Region IV
60 8th Street, N.E.
Atlanta, Georgia 30309

June 26, 1990

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mark Graham, President
Graham Enterprises, Inc.
6000 H Unity Drive
Norcross, Georgia 30071

REGULATORY LETTER

Dear Mr. Graham:

During an investigation of your firm located at 6000 H Unity Drive, Norcross, Georgia on February 15 and 16, 1990, our Investigators found that your firm markets the "Diet TEC 90" program consisting of the products "Master Formula Diet TEC 90 Tablets" and "Herbal-Fiber Formula Diet TEC 90". Master Formula Diet TEC 90 is labeled as containing, Chromium (as Picolinate), Chromium (as Polynicotinate) and various vitamins, minerals and herbs. The label for the Herbal-Fiber Formula Diet TEC 90 indicates the primary ingredients are herbs with potassium and fiber.

Labeling for the two products includes a "DIET-TEC 90 PROGRESS REPORT" with a blank for filling in the users "WEIGHT LOSS" at the end of a 12 week program of use; a promotional sheet entitled "DIET-TEC 90" containing such claims as "*** IN MANY CASES LOWERS SERUM CHOLESTEROL *** REDUCES INCIDENCE OF COLON CANCER *** AIDS IN REGULATION OF BLOOD SUGAR ***, "REDUCTION OF FAT CELLS INCREASED BY THREE TIMES", and "PROVIDES A FULL FEELING TO REDUCE HUNGER"; a promotional sheet entitled "Side Effect Reported by Many CHROMIUM PICOLINATE USERS: WEIGHT LOSS" containing such statements as "HOW CHROMIUM PICOLINATE HELPS YOU LOSE WEIGHT", Better Appetite Control", and "...calories are burned more rapidly so that weight loss is easier..."; a "GRAHAM ENTERPRISES, INC." referral sheet for "DIET-TEC 90" containing such statements as "NOT ONLY WILL YOU LOSE WEIGHT...", a "GRAHAM ENTERPRISES, INC." appreciation and as "DIET-TEC 90 does represent the latest in weight control programs" and weight loss and body toning are only the visible results you will experience on this program."

Your script used by salespersons during telephone sales includes statements such as "I am calling because I understand you are serious about losing a few pounds..,.I have some great news for you _____ I'm going to offer you the opportunity to participate

in an exclusive monitoring program using a revolutionary new product called Diet TEC 90... How much weight do you feel you need to lose? Are you committed to losing that weight?... Great, _____ you sound like an ideal candidate for this program. ... let me tell you what Diet Tec 90 is all about ...."

Because such labeling includes statements which represent and suggest that these articles are intended to be used in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man, these products are drugs within the meaning of Section 201(g) of the Federal Food, Drug, and Cosmetic Act. Under the agency's general regulatory policy governing OTC products during the pendency of the OTC Review, OTC products may be permitted to be marked without the risk of regulatory action provided:

1) The product or similarly formulated and labeled products are marketed as OTC drugs at the inception of the OTC Review (May 11, 1972), a date that was then extended to on or before December 4, 1975 (21 CFR 330.13).

2) Such product does not constitute a hazard to health.

3) The product formulation is not regarded to be a prescription drug within the meaning of 503(b).

4) It is an OTC drug and does not bear claims for serious disease conditions that require the attention and supervision of a licensed practitioner.

Therefore, because Master Formula Diet TEC 90 Tablets and Herbal-Fiber Formula Diet TEC 90 Tablets both fail to meet the criteria within the general regulatory policy, and because we are unaware of any substantial scientific evidence which documents that the drugs are generally recognized as safe and effective for use under the conditions prescribed, recommended or suggested in the labeling, these drugs are new drugs within the meaning of Section 201(p). Accordingly, marketing of these drugs is a violation of the Federal Food, Drug, and Cosmetic Act as follows:

SECTION	BRIEF DESCRIPTION
505(a)	The articles are drugs within the meaning of Section 201(g) of the Act which may not be introduced or delivered for introduction into interstate commerce under Section 505(a) of the Federal Food, Drug, and Cosmetic Act, since they are new drugs within the meaning of Section 201(p) of the Act and no approval of any applications filed pursuant to Section 505(b) are effective for such drugs.

502(a)	The articles of drug are further misbranded in that their labeling is false and misleading by suggestions and representations that the articles are safe and effective in lowering serum cholesterol, in reducing the incidence of colon cancer, in aiding in the regulation of blood sugar, and in reducing weight and suppressing appetite.
502(f)(1)	The articles of drug are further misbranded in that their labeling fails to bear adequate directions for use for the conditions for which the articles are represented or suggested, and they are not exempt from this requirement under Regulation 21 CFR 201.115 since the articles are new drugs within the meaning of Section 201(p) and no approval of any application filed pursuant to Section 505(b) are effective for these drugs.

Because the labels for the products represent them to be dietary/nutritional supplements, these products are further in violation of the Federal Food, Drug, and Cosmetic Act as follows:

HERBAL-FIBER FORMULA

SECTION	BRIEF DESCRIPTION
403(a)(1)	The product identified as Herbal-Fiber Formula Diet TEC 90 bears declarations of several ingredients, namely, buchuleaves, hydrangea leaves, couch grass, uva ursi, saw palmett, juniper berry, green corn silk, stearic acid, microcellulose fiber and guar fiber according to potency, which may falsely mislead consumers to believe that all of the ingredients are essential nutrients, whereas, only two ingredients (potassium and magnesium) are essential nutrients and only one (magnesium) has an established U.S. RDA.
403(a)(2) 101.3(b)	The label for the product identified as Herbal-Fiber Formula Diet TEC 90 fails to bear an appropriate identity statement for the food, e.g., dietary supplement of potassium or potassium supplement.
403(a)(2)	The label lists ingredients, buchuleaves, hydrangea leaves, couch grass, uva ursi, saw

palmett, juniper berry, green corn silk, stearic acid, microcellulose fiber and guar fiber which are not vitamins or minerals, other than as part of a list of all the ingredients and gives prominences or emphasizes such ingredients as to represent them as sources of vitamins or minerals.

Additionally, the label bears several ingredients that have not been affirmed as GRAS by the Food and Drug Administration and there are not food additive regulations providing for their safe use, namely buchuleaves, hydrangea leaves, couch grass, saw palmett, and uva ursi.

The ingredient "potassium (element)", "microcellulose fiber" and "guar fiber" shall be declared on the label by their common or usual names.

The label makes a hypoallergenic claim, but fails to clearly reveal the specific plant of animal that is the source of such food ingredient, in accordance with 21 CFR 105.62.

The statement "... contains no ... corn ..." may be misleading since the label lists "green corn silk" as a component of this product.

The content of the tablet is not prominently declared due to the size of type.

MASTER FORMULA

SECTION	BRIEF DESCRIPTION
403(a)(1)	The product identified as Master Formula Diet TEC 90 declares the ingredients, namely, inositol (as inositol) methanine, chromium, stearic acid, rehmaniae glutinara herb), atractylodes lance, fiber (microcellulose) in the food according to potency which may mislead consumers to believe that all of these ingredients are essential nutrients, whereas, niacin, magnesium, and Vitamin B_6 are the only essential nutrients in the product for which U.S. RDA's have been established.
403(i)(1) 21 CFR 101.3(b)	The label for the product identified as Master Formula Diet TEC 90 fails to bear an appropriate common or usual name for this product, e.g., dietary supplement of niacin, Vitamin B_6 and chromium.
403(a)(2)	The label lists ingredients, namely, inositol (as Inositol), methonine, stearic acid,

rehmaniae glutinara (herb), atractylodes lance, fiber (microcellulose) which are not vitamins or minerals, other than as part of a list of all the ingredients and gives prominence to or emphasizes ingredients as to represent them as sources of vitamins and minerals.

Additionally, the product label declares the ingredients, rehmaniae glutinara, and atractylodes lance which have not been affirmed as GRAS and there are no food additive regulations providing for their safe use in foods.

The ingredient declared as "fiber (microcellulose)" shall be declared by its specific common or usual name.

The label makes a hypoallergenic claim, but fails to clearly reveal the specific plant or animal that is the source of this food.

The content of the tablet is not prominently declared due to the size of type.

The above enumeration of deficiencies should not be construed as an all inclusive list of violations which may be in existence with your products. It is your responsibility to ensure that all requirements of the Federal Food, Drug, and Cosmetic Act and Regulations promulgated thereunder are being met.

We request that you take prompt action to correct these violations. If such action is not taken, the Food and Drug Administration is prepared to invoke appropriate regulatory sanctions such as seizure or injunction (21 U.S.C. 332 and 334).

Please advise us within ten (10) days as to the specific actions you have taken or intend to take, including measures to prevent the recurrence of the violations, and an explanation of any potential delays in correcting the violations that may occur. Your reply should be directed to Daryl J Thompson, Compliance Officer, Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309.

Sincerely,

John H. Turner, Director
Atlanta District