



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

DEC 22 2000

101 JUN -22 9 57 AM

Mr. Isreal Brecher  
Maxi Health Research, Inc.  
1309 Avenue U  
Brooklyn, New York 11229

Dear Mr. Brecher:

This is in response to your letter to the Food and Drug Administration (FDA), dated November 27, 2000, pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Maxi Health Research, Inc. is making the following claims, among others, for the following products:

**Chromium Supreme Dietary Supplement**

"...maintain healthy blood sugar levels"

**Maxi B50 Dietary Supplement**

"...maintain normal regulation of cholesterol and sugar levels..."

**Chewable Calcium Complex Dietary Supplement**

"...clotting the blood"

**Maxi Cal 1000 Dietary Supplement**

"It plays a role in ...clotting the blood"

**Chewable Maxi Health Children's Multi Dietary Supplement**

"For support for healthy blood clotting"

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate diseases, namely hypercholesterolemia, disorders of glucose metabolism, and, and disorders of platelet aggregation and blood clotting. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

978-0163

LET 434

Page 2 - Mr. Isreal Brecher

Please contact us if we may be of further assistance.

Sincerely,

John B. Foret  
Director  
Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

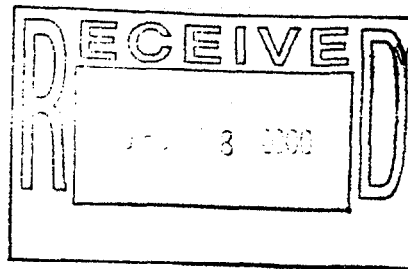
Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, New York District Office, Compliance Branch, HFR-NE140

cc:

HFA-224 (w/incoming)  
HFA-305 (docket 97S-0163)  
HFS-22 (CCO)  
HFS-800 (file, r/f)  
HFS-810  
HFS-811 (file)  
HFD-40 (Behrman)  
HFD-310  
HFD-314 (Aronson)  
HFS-605  
HFV-228 (Betz)  
GCF-1 (Nickerson)  
f/t:rjm:HFS-811:12/20/00:73758.adv:disc53

1309 Avenue U  
Brooklyn, NY 11229  
1-800-895-9555



Main Office: 1-800-544-6294  
In NY: 718-645-6800  
FAX: 718-645-3333

November 27, 2000

Office of Nutritional Products, Labeling and Dietary Supplements (ONPLDS)  
HFS-810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C St. SW  
Washington DC 20204

**Statement of Nutritional Support- Chewable Maxi Health Children's Multi**

Pursuant to 21 CFR Part 101.93, Maxi Health Research, Inc. is filing the following Statement of Nutritional Support for the Dietary Supplement marketed as Chewable Maxi Health Children's Multi:

- 1) Name and Address of Distributor: Maxi Health Research, Inc., 1309 Avenue U Brooklyn New York 11229
- 2) Text of Nutritional Support Statement being made: "...to assure that your children are getting the nutrients they need to stay healthy...  
. to help maintain a healthy digestive tract  
. for healthy hair, skins and nails  
. for a healthy nervous system, blood cells and enzymes  
. for support for healthy blood clotting;  
. for immune support and to protect your cells from damage due to free radicals. "
- 3) Name of dietary ingredient: Vitamins A, B complex, C, D, E with Enzymax<sup>®</sup>, a registered trademark of a vital digestive enzyme complex that aids digestion.
- 4) Brand Name: Chewable Maxi Health Children's Multi Dietary Supplement
- 5) Substantiation information on file at the company office. The corporate officer who can certify same is Isreal Brecher VP of Sales & Marketing

Yours truly,  
  
Isreal Brecher  
Maxi Health Research Inc.

73758



1309 Avenue U  
Brooklyn, NY 11229  
1-800-895-9555

**Chewable Maxi Health Cherry Tablets**

Main Office: 1-800-544-6294  
In NY: 718-645-6800  
FAX: 718-645-3333

| Supplement Facts   |               |       |
|--|---------------|-------|
| Serving Size 3 Tablets   |               |       |
| Servings Per Container (enter number)  |               |       |
| Amount Per Serving   | % Daily Value |       |
| Calories   | 18            |       |
| Total carbohydrates  | 4g            | 1%**  |
| Sugars   | 4g            | *     |
| Vitamin A<br>(50% as Betatene <sup>®1</sup> D. Salina <sup>®1</sup> natural mixed carotenoids, 50% as palmitate) | 5000 IU       | 100%  |
| Vitamin C (as ascorbic acid)   | 250 mg        | 417%  |
| Vitamin D (as cholecalciferol)   | 300 IU        | 75%   |
| Vitamin E (as d-alpha tocopheryl succinate)  | 75 IU         | 250%  |
| Vitamin K (as phytonadione)  | 50 mcg        | 62%   |
| Thiamin (Vitamin B-1) (as thiamine HCl)  | 10 mg         | 667%  |
| Riboflavin (Vitamin B-2)   | 10 mg         | 588%  |
| Niacin (Vitamin B-3) (as niacinamide)  | 50 mg         | 250%  |
| Vitamin B-6 (as pyridoxine HCl)  | 20 mg         | 1000% |
| Folic acid   | 100 mcg       | 25%   |
| Vitamin B-12 (as cyanocobalamin)   | 100 mcg       | 1667% |
| Biotin   | 100 mcg       | 33%   |
| Pantothenic acid (as d-calcium pantothenate)   | 20 mg         | 200%  |
| Calcium (as calcium carbonate)   | 80 mg         | 8%    |
| Iron (as iron amino acid chelate)  | 10 mg         | 55%   |
| Magnesium (as magnesium amino acid chelate)  | 10 mg         | 2%    |
| Zinc (as zinc amino acid chelate)  | 5 mg          | 33%   |
| Selenium (as selenium amino acid chelate)  | 10 mcg        | 14%   |
| Copper (as copper amino acid chelate)  | 250 mcg       | 12%   |
| Manganese (as manganese amino acid chelate)  | 2 mg          | 100%  |
| Chromium (as Chromemate <sup>®2</sup> chromium polynicotinate)   | 50 mcg        | 42%   |
| Potassium (as potassium amino acid complex)  | 2 mg          | < 1%  |

|  |         |   |
|--|---------|---|
| Bee pollen powder  | 30 mg   | * |
| Choline (as choline bitartrate)                                | 40 mg   | * |
| Inositol   | 40 mg   | * |
| Lactobacillus acidophilus (providing 1 million live organisms) | 810 mcg | * |
| Lemon bioflavonoid complex powder                              | 10 mg   | * |
| PABA ( <i>para</i> -aminobenzoic acid)                         | 10 mg   | * |
| Papaya powder ( <i>Carrica papaya</i> ) (fruit)                | 30 mg   | * |

\* Daily Value not established.

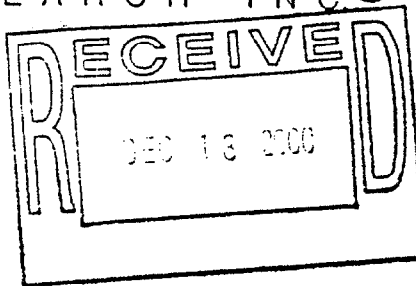
\*\* Daily Value based on a 2,000 calorie per day diet.

Other ingredients: Sucrose, fructose, vegetable stearine, natural strawberry flavor, natural cherry flavor, magnesium stearate, silicon dioxide, Enzymax<sup>®</sup> (bromelain, papain, lipase, amylase, protease).

Enzymax<sup>®</sup> is a registered trademark of Maxi Health.

- 1- Betatene<sup>®1</sup> and D. Salina<sup>®1</sup> are registered trademarks of Betatene Pty. Ltd., a Henkel Company.
- 2- Chromemate<sup>®2</sup>, a patented, biologically active oxygen-coordinated niacin-bound chromium complex, is a trademark of InterHealth Nutritionals Inc., U.S. Patents No. 4,923,855; 4,954,492; 5,194,615.)

1309 Avenue U  
Brooklyn, NY 11229  
1-800-895-9555



Main Office: 1-800-544-6294  
In NY: 718-645-6800  
FAX: 718-645-3333

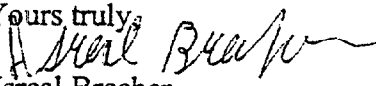
November 27, 2000

Office of Nutritional Products, Labeling and Dietary Supplements (ONPLDS)  
HFS-810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C St. SW  
Washington DC 20204

**Statement of Nutritional Support - Maxi Cal 1000.**

Pursuant to 21 CFR Part 101.93, Maxi Health Research, Inc. is filing the following Statement of Nutritional Support for the Dietary Supplement marketed as Maxi Cal 1000:

- 1) Name and Address of Distributor: Maxi Health Research, Inc., 1309 Avenue U, Brooklyn, New York 11229
- 2) Text of Nutritional Support Statement being made: "...to maintain a healthy heart, strong bones, the proper functioning of the electrical impulses that control your muscles, and give you the ability to function at your best... to maintain healthy blood levels of calcium... It is necessary for healthy bones and teeth. Magnesium is needed to maintain healthy bone and muscle. It plays a role in making new cells, clotting the blood, forming the cellular energy the body needs to function and supports the healthy function of the pancreas. To restore magnesium depleted due to some prescription drugs...to maintain healthy hormone levels, neurotransmitters and optimum heart function."
- 3) Name of dietary ingredient: Calcium, Magnesium, Vitamin D3 with Enzymax®, a registered trademark of a vital digestive enzyme complex that aids digestion,
- 4) Brand Name: Maxi Cal 1000 Dietary Supplement
- 5) Substantiation information on file at the company office. The corporate officer who can certify same is Isreal Brecher, VP of Sales & Marketing

Yours truly,  
  
Isreal Brecher  
Maxi Health Research Inc.

73758

Maxi Health / Maxi Cal 1000 Vegicaps

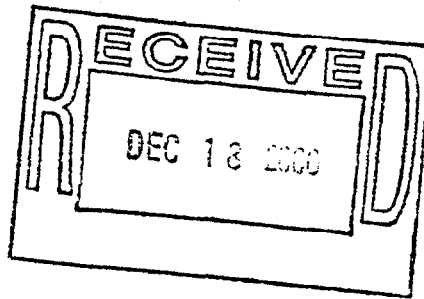
| Supplement Facts                        |               |      |
|---|---------------|------|
| Serving Size 4 Capsules                 |               |      |
| Servings Per Container (enter number)   |               |      |
| Amount Per Serving                      | % Daily Value |      |
| Vitamin D (as cholecalciferol)          | 400 IU        | 100% |
| Calcium (as calcium carbonate, citrate) | 1000 mg       | 100% |
| Magnesium (as magnesium oxide)          | 500 mg        | 100% |
| *Daily Value not established            |               |      |

Other ingredients: Vegetable cellulose, magnesium stearate, Enzymax<sup>®</sup> (bromelain, papain, lipase, amylase, protease), glycerin.

Enzymax<sup>®</sup> is a registered trademark of Maxi Health.

1309 Avenue U  
Brooklyn, NY 11229  
1-800-895-9555

Main Office: 1-800-544-6294  
In NY: 718-645-6800  
FAX: 718-645-3333



November 27, 2000

Office of Nutritional Products, Labeling and Dietary Supplements (ONPLDS)  
HFS-810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C St. SW  
Washington DC 20204

**Statement of Nutritional Support - Chewable Calcium Complex**

Pursuant to 21 CFR Part 101.93, Maxi Health Research, Inc. is filing the following Statement of Nutritional Support for the Dietary Supplement marketed as Chewable Calcium Complex:

- 1) Name and Address of Distributor: Maxi Health Research, Inc., 1309 Avenue U. Brooklyn, New York 11229
- 2) Text of Nutritional Support Statement being made: "...to help you maintain healthy bones and teeth...to maintain healthy muscle function...new cells, clotting the blood, forming the cellular energy the body needs to function and supports the healthy function of the pancreas." "... for maintaining healthy hormone levels, neurotransmitters and optimum heart function."
- 3) Name of dietary ingredient: Calcium, Magnesium with Enzymax<sup>®</sup>, a registered trademark of a vital digestive enzyme complex that aids digestion.
- 4) Brand Name: Chewable Calcium Complex Dietary Supplement
- 5) Substantiation information on file at the company office. The corporate officer who can certify same is Isreal Brecher, VP of Sales & Marketing

Yours truly,  
Isreal Brecher  
Maxi Health research Inc.

73758



Maxi Health / Chewable Calcium Complex Tablets

| Supplement Facts                                      |                 |      |
|---|-----------------|------|
| Serving Size 4 Tablets                                |                 |      |
| Servings Per Container (enter number)                 |                 |      |
| Amount Per Serving                                    | % Daily Value** |      |
| Calories  | 24              |      |
| Total Carbohydrates                                   | 5.6 g           | 2%   |
| Sugars  | 5.6 g           | *    |
| Calcium (as calcium carbonate, citrate)               | 1000 mg         | 100% |
| Magnesium (as magnesium oxide, amino acid chelate)    | 200 mg          | 50%  |
| * Daily Value not established.                        |                 |      |
| ** Daily Value based on a 2,000 calorie per day diet. |                 |      |

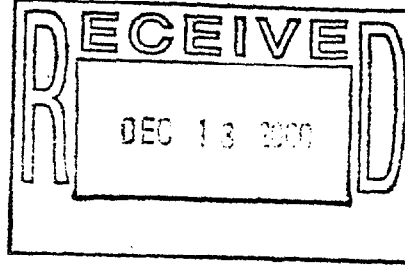
Other ingredients: Sucrose, fructose, vegetable stearine, natural vanilla flavor, Enzymax® (bromelain, papain, lipase, amylase, protease).

Enzymax® is a registered trademark of Maxi Health.



1309 Avenue U  
Brooklyn, NY 11229  
1-800-895-9555

Main Office: 1-800-544-6294  
In NY: 718-645-6800  
FAX: 718-645-3333



November 27, 2000

Office of Nutritional Products, Labeling and Dietary Supplements (ONPLDS)  
HFS-810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C St. SW  
Washington DC 20204

**Statement of Nutritional Support - Maxi B50**

Pursuant to 21 CFR Part 101.93, Maxi Health Research, Inc. is filing the following Statement of Nutritional Support for the Dietary Supplement marketed as Maxi B50:

1) Name and Address of Distributor: Maxi Health Research, Inc., 1309 Avenue U, Brooklyn, New York 11229

2) Text of Nutritional Support Statement being made: "... high potency synergistic combination of all the B vitamins so essential to your health... supports the healthy function of your nerves, heart and muscles and boosts your stamina... helps you metabolize carbohydrates, fats and proteins, supports healthy eyes and skin and aids in the production of hormones... assists the digestive system in maintaining healthy function and helps metabolize the foods you eat, providing you with energy,... supports a healthy immune system... the formation of hemoglobin,...necessary to build the genetic material of your cells in conjunction with folic acid... It is a key ingredient in... enzymes,... healthy growth and development and enhances the effectiveness of Vitamin B12... to make cellular membranes...to maintain proper electrical energy and nutrient transfer across the cell membrane. ... a precursor of acetylcholine, a stimulatory neurotransmitter... helps in the production of lipotropic agents, which convert fats into fuel, and in the production of HDL (good) cholesterol...help you maintain a healthy circulatory system and maintain normal regulation of cholesterol and sugar levels...supports... normal mental function..."



3) Name of dietary ingredient: Vitamins B1,2,3, 5, 6 &12, Biotin, Folic Acid, Inositol, Choline, and PABA and Enzymax® is a registered trademark of a vital digestive enzyme complex that aids digestion.

4) Brand Name: Maxi B50 Dietary Supplement

5) Substantiation information on file at the company office. The corporate officer who can certify same is Isreal Brecher, VP of Sales & Marketing

Yours truly,  
  
Isreal Brecher  
Maxi Health Research Inc.

73798

Maxi Health / Maxi B-50 Complex Capsules

| Supplement Facts                                |        |               |
|---|--------|---------------|
| Serving Size 1 Capsule                          |        |               |
| Servings Per Container (enter number)           |        |               |
| Amount Per Serving                              |        | % Daily Value |
| Thiamin (Vitamin B-1) (as thiamine mononitrate) | 50 mg  | 3333%         |
| Riboflavin (Vitamin B-2)                        | 50 mg  | 2941%         |
| Niacin (Vitamin B-3) (as niacinamide)           | 50 mg  | 250%          |
| Vitamin B-6 (as pyridoxine HCl)                 | 50 mg  | 2500%         |
| Folic acid                                      | 50 mcg | 13%           |
| Vitamin B-12 (as cyanocobalamin)                | 50 mcg | 833%          |
| Biotin  | 50 mcg | 17%           |
| Pantothenic acid (as d-calcium pantothenate)    | 50 mg  | 500%          |
| <i>para</i> -aminobenzoic acid                  | 50 mg  | *             |
| Choline (as choline bitartrate)                 | 50 mg  | *             |
| Inositol  | 50 mg  | *             |

\* Daily Value not established

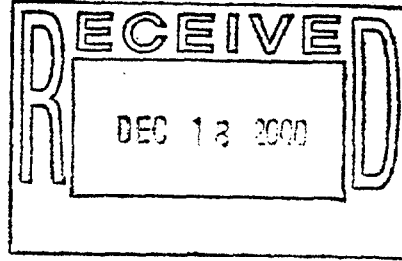
Other ingredients: Vegetable cellulose, magnesium stearate, Enzymax<sup>®</sup> (bromelain, papain, lipase, amylase, protease), glycerin.

Enzymax<sup>®</sup> is a registered trademark of Maxi Health.



1309 Avenue U  
Brooklyn, NY 11229  
1-800-895-9555

Main Office: 1-800-544-6294  
In NY: 718-645-6800  
FAX: 718-645-3333



November 27, 2000

Office of Nutritional Products, Labeling and Dietary Supplements (ONPLDS)  
HFS-810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C St. SW  
Washington DC 20204

**Statement of Nutritional Support- Chromium Supreme**

Pursuant to 21 CFR Part 101.93, Maxi Health Research, Inc. is filing the following Statement of Nutritional Support for the Dietary Supplement marketed as Chromium Supreme:

- 1) Name and Address of Distributor: Maxi Health Research, Inc., 1309 Avenue U Brooklyn New York 11229
- 2) Text of Nutritional Support Statement being made "...Chromium with Vanadium, Selenium, Zinc and Manganese for the health and maintenance of normal metabolism... supports the healthy metabolism of proteins, carbohydrates and fats... helps transport blood sugar into the cells and so it helps maintain healthy blood sugar levels. To support a healthy immune system, energy metabolism and longevity..."
- 3) Name of dietary ingredient: Chromate Brand Chromium (chromium, niacin, cysteine), Vanadium, Selenium, Zinc, Manganese with Enzymax®, a registered trademark of a vital digestive enzyme complex that aids digestion
- 4) Brand Name: Chromium Supreme Dietary Supplement
- 5) Substantiation information on file at the company office. The corporate officer who can certify same is Isreal Brecher VP of Sales & Marketing

Yours truly,

Isreal Brecher  
Maxi Health Research Inc.

73758

## Maxi Health / Chromium Supreme Tablet

| Supplement Facts                                  |               |      |
|---|---------------|------|
| Serving Size 1 Tablet                             |               |      |
| Servings Per Container (enter number)             |               |      |
| Amount Per Serving                                | % Daily Value |      |
| Zinc (as zinc amino acid chelate)                 | 10 mg         | 67%  |
| Selenium (as selenium amino acid chelate)         | 10 mcg        | 14%  |
| Manganese (as manganese amino acid chelate)       | 10 mg         | 500% |
| Chromium (as Chromemate® chromium polynicotinate) | 100 mcg       | 83%  |
| Vanadium (as vanadyl sulfate)                     | 50 mcg        | *    |
| *Daily Value not established                      |               |      |

Other ingredients: Microcrystalline cellulose, vegetable stearine, modified cellulose gum, Enzymax® (bromelain, papain, lipase, amylase, protease), vegetable protein.

Chromemate®, a patented, biologically active oxygen-coordinated niacin-bound chromium complex, is a trademark of InterHealth Nutritionals Inc., U.S. Patents No. 4,923,855; 4,954,492; 5,194,615.

Enzymax® is a registered trademark of Maxi Health.