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 &
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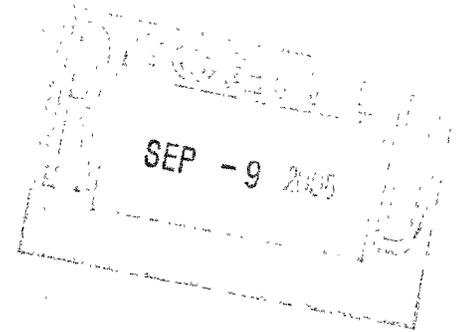
9755 SW Commerce Circle, Suite B2
 Wilsonville, OR 97070
 P: 503.582.8386 • F: 503.582.0467

825 Challenger Drive, Green Bay, WI 54311-8328
 P: 920.469.1313 • F: 888.570.6460 (Enzymatic)
 P: 920.469.9099 • F: 920.469.4418 (Phyto)

0169 5 SEP 22 P2:21

August 23, 2005

Office of Nutritional Products, Labeling &
 Dietary Supplements, HFS 810
 Center for Food Safety and Applied Nutrition
 Food and Drug Administration
 5100 Paint Branch Parkway
 College Park, MD 20740



RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL-RX™*	Clinically shown to maintain healthy cholesterol already within normal range.*	Vitamin C (ascorbic acid), Vitamin E (mixed d-alpha tocopherols), Niacin (niacinamide), Vitamin B6 (pyridoxine HCl), Folic Acid, Vitamin B12 (cyanocobalamin), Magnesium, L-Selenomethionine, L-Arginine HCl, Carnitine, CoQ10, Policosanol, Hawthorn Berry Extract, Taurine, Garlic, Grape Seed Extract, Grape Skin Extract, N-acetyl-L-cysteine, Alpha Lipoic Acid, Soy Isoflavones, Tocotrienols

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert Doster
 Robert Doster
 Title: Senior Vice President of Scientific Affairs
 Date: 8/23/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux
 Michael P. Devereux
 Chief Financial Officer

975 0162 LET 16667



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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL-RX™*	Clinically shown to maintain healthy triglyceride levels already within normal ranges.*	Vitamin C (ascorbic acid), Vitamin E (mixed d-alpha tocopherols), Niacin (niacinamide), Vitamin B6 (pyridoxine HCl), Folic Acid, Vitamin B12 (cyanocobalamin), Magnesium, L-Selenomethionine, L-Arginine HCl, Carnitine, CoQ10, Policosanol, Hawthorn Berry Extract, Taurine, Garlic, Grape Seed Extract, Grape Skin Extract, N-acetyl-L-cysteine, Alpha Lipoic Acid, Soy Isoflavones, Tocotrienols

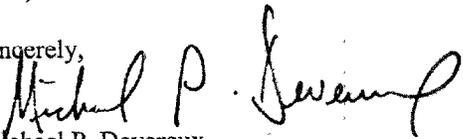
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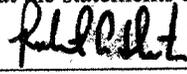
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL-RX™*	Clinically shown to increase good cholesterol (HDL-2) levels.*	Vitamin C (ascorbic acid), Vitamin E (mixed d-alpha tocopherols), Niacin (niacinamide), Vitamin B6 (pyridoxine HCl), Folic Acid, Vitamin B12 (cyanocobalamin), Magnesium, L-Selenomethionine, L-Arginine HCl, Carnitine, CoQ10, Policosanol, Hawthorn Berry Extract, Taurine, Garlic, Grape Seed Extract, Grape Skin Extract, N-acetyl-L-cysteine, Alpha Lipoic Acid, Soy Isoflavones, Tocotrienols

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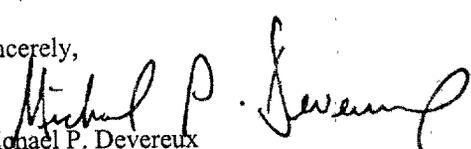
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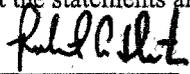
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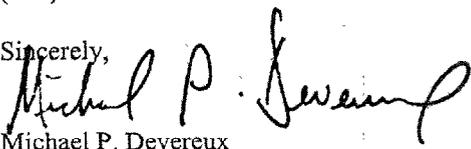
PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL-RX™*	Clinically shown to reduce CRP (C-Reactive Protein) levels.*	Vitamin C (ascorbic acid), Vitamin E (mixed d-alpha tocopherols), Niacin (niacinamide), Vitamin B6 (pyridoxine HCl), Folic Acid, Vitamin B12 (cyanocobalamin), Magnesium, L-Selenomethionine, L-Arginine HCl, Carnitine, CoQ10, Policosanol, Hawthorn Berry Extract, Taurine, Garlic, Grape Seed Extract, Grape Skin Extract, N-acetyl-L-cysteine, Alpha Lipoic Acid, Soy Isoflavones, Tocotrienols

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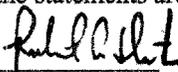
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	Shown in a clinical study conducted at Scripps Memorial Hospital to raise HDL (good cholesterol) levels*	Vitamin C (ascorbic acid), Vitamin E (mixed d-alpha tocopherols), Niacin (niacinamide), Vitamin B6 (pyridoxine HCl), Folic Acid, Vitamin B12 (cyanocobalamin), Magnesium (from Magnesium amino acid chelate), Selenium (L-Selenomethionine), L-Arginine (from L-arginine HCl), L-Carnitine (from L-carnitine L-tartrate), Coenzyme Q10 (CoQ10) (ubiquinone 10), Policosanol, Hawthorn Berry Extract, Taurine, Garlic, Grape Seed Extract, Grape Skin Extract, N-acetyl-L-cysteine, Alpha Lipoic Acid, Soy Isoflavones, Tocotrienols

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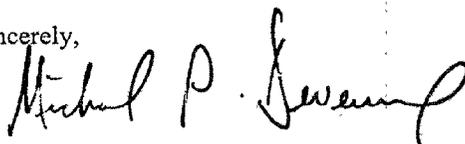
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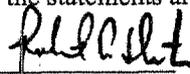
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	Levels of HDL2 (best cholesterol) rose up to 21%.*	Vitamin C (ascorbic acid), Vitamin E (mixed d-alpha tocopherols), Niacin (niacinamide), Vitamin B6 (pyridoxine HCl), Folic Acid, Vitamin B12 (cyanocobalamin), Magnesium (from Magnesium amino acid chelate), Selenium (L-Selenomethionine), L-Arginine (from L-arginine HCl), L-Carnitine (from L-carnitine L-tartrate), Coenzyme Q10 (CoQ10) (ubiquinone 10), Policosanol, Hawthorn Berry Extract, Taurine, Garlic, Grape Seed Extract, Grape Skin Extract, N-acetyl-L-cysteine, Alpha Lipoic Acid, Soy Isoflavones, Tocotrienols

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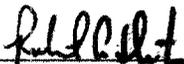
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HDL RX™*	An HDL reading above 60 is now recognized as having a positive impact on heart health.*	Vitamin C (ascorbic acid), Vitamin E (mixed d-alpha tocopherols), Niacin (niacinamide), Vitamin B6 (pyridoxine HCl), Folic Acid, Vitamin B12 (cyanocobalamin), Magnesium (from Magnesium amino acid chelate), Selenium (L-Selenomethionine), L-Arginine (from L-arginine HCl), L-Carnitine (from L-carnitine L-tartrate), Coenzyme Q10 (CoQ10) (ubiquinone 10), Policosanol, Hawthorn Berry Extract, Taurine, Garlic, Grape Seed Extract, Grape Skin Extract, N-acetyl-L-cysteine, Alpha Lipoic Acid, Soy Isoflavones, Tocotrienols

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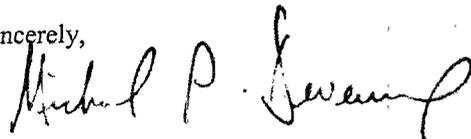
PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	Niacin aids in fat and cholesterol metabolism, which supports healthy blood circulation.*	Vitamin C (ascorbic acid), Vitamin E (mixed d-alpha tocopherols), Niacin (niacinamide), Vitamin B6 (pyridoxine HCl), Folic Acid, Vitamin B12 (cyanocobalamin), Magnesium (from Magnesium amino acid chelate), Selenium (L-Selenomethionine), L-Arginine (from L-arginine HCl), L-Carnitine (from L-carnitine L-tartrate), Coenzyme Q10 (CoQ10) (ubiquinone 10), Policosanol, Hawthorn Berry Extract, Taurine, Garlic, Grape Seed Extract, Grape Skin Extract, N-acetyl-L-cysteine, Alpha Lipoic Acid, Soy Isoflavones, Tocotrienols

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert Doster
Robert Doster
Title: Senior Vice President of Scientific Affairs

Date: 8/25/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux
Chief Financial Officer



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August 25, 2005

Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HDL RX™*	Allows you to be proactive in your effort to improve good cholesterol levels and heart health.*	Vitamin C (ascorbic acid), Vitamin E (mixed d-alpha tocopherols), Niacin (niacinamide), Vitamin B6 (pyridoxine HCl), Folic Acid, Vitamin B12 (cyanocobalamin), Magnesium (from Magnesium amino acid chelate), Selenium (L-Selenomethionine), L-Arginine (from L-arginine HCl), L-Carnitine (from L-carnitine L-tartrate), Coenzyme Q10 (CoQ10) (ubiquinone 10), Policosanol, Hawthorn Berry Extract, Taurine, Garlic, Grape Seed Extract, Grape Skin Extract, N-acetyl-L-cysteine, Alpha Lipoic Acid, Soy Isoflavones, Tocotrienols

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert Doster

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 8/25/05

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Sincerely,

Michael P. Devereux
Chief Financial Officer