

Public Health Service

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Food and Drug Administration Washington, DC 20204

SEP 19 200

Mr. Lizhen Wei General Manager AZ Best Friend, Inc. 2038 B N 16th Street Phoenix, Arizona 85006

Dear Mr. Wei:

This is in response to your letter of August 22, 2001 to the Food and Drug Administration (FDA) 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 AZ Best Friend, Inc. is making the following claims, among others, for the following products:

Dia Complete 500™

"Helps maintain normal blood sugar ... "

Ret-Rooted 500™

"Helps...maintain normal blood cholesterol"

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 and disorders of blood sugar regulation. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are 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.

975-0163

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Please contact us if you require further assistance.

Sincerely,

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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, Los Angeles District Compliance, HFR-PA240

AZ BEST FRIEND, INC.

2038 B N 16th Street, Phoenix, AZ 85006 Telephone: 480-860-4182 Fax: 480-551-4918

August 22, 2001

The Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C St. SW Washington, DC 20204



Re: Notification for Certain Types of Statements on Dietary Supplements

Dear Sir or Madam:

Pursuant to \$403(r)(6) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. \$343(r)(6) and 21 CFR \$101.93 of FDA's regulations, we hereby notify you that we are using the following statements:

(1) The name and address of the distributor:

AZ Best Friend, Inc., 2038 B N 16th St., Phoenix, AZ 85006

(2) The text of the statement that is being made:

Helps maintain normal blood sugar and support healthy immune function.

(3) The name of the dietary ingredient or supplement:

Ginseng, Astragalus, Huang-Lian, Pueraria, Figwort, Persica, San-Qi Ginseng, Chinese Rhubarb, Gypsum.

(4) The name of the dietary supplement:

Dia Complete 500™

(5) The following disclaimer appears on the label in bold:

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

I certify that the information contained in this notice is complete and accurate and that AZ BEST FRIEND, INC. has substantiation that these statements are truthful and not misleading.

Respectfully submitted,

General Manager AZ Best Friend, Inc.

AZ BEST FRIEND, INC.

2038 B N 16th Street, Phoenix, AZ 85006 Telephone: 480-860-4182 Fax: 480-551-4918

August 22, 2001

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Dear Sir or Madam:

Pursuant to 403(r)(6) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 343(r)(6) and 21 CFR 101.93 of FDA's regulations, we hereby notify you that we are using the following statements:

(1) The name and address of the distributor:

AZ Best Friend, Inc., 2038 B N 16th St., Phoenix, AZ 85006

(2) The text of the statement that is being made:

Helps maintain healthy circulation to the brain and legs and maintain normal blood cholesterol.

(3) The name of the dietary ingredient or supplement:

Red-Rooted Sage, San-Qi, Persica, Safflower, Curcuma, Paniculate Swallowwort,

Chinese Howthorn, Job's Tears, Chinese Rhubarb.

(4) The name of the dietary supplement:

Ret-Rooted 500™

(5) The following disclaimer appears on the label in bold:

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

I certify that the information contained in this notice is complete and accurate and that AZ BEST FRIEND, INC. has substantiation that these statements are truthful and not misleading.

Respectfully submitted,

General Manager AZ Best Friend, Inc.

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