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MAR 14 2006

Mr. Kevin Smith
President
RKS, Inc.
6306 215th Street Southwest
Mountlake Terrace, Washington 98043

Dear Mr. Smith:

This is in response to your letter of February 7, 2006 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 RKS, Inc. is making the following claims, among others, for the products **LifeMag** and **Magnesium Plus**:

“Magnesium helps to maintain healthy...blood sugar levels... blood pressure....”

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because “many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease,” in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The same principle applies to claims about the control of blood sugar levels and blood pressure; that is, claims that do not establish that the claims are about blood sugar levels and blood pressures that are already within normal limits imply that the products are intended to treat abnormal blood sugar levels and elevated blood pressure (hypertension), which are diseases. Therefore, because the claims you are making for these products represent that the products are intended to affect blood sugar levels and blood pressure but do not also include statements about them being intended to affect blood sugar levels and blood pressure that are already in the normal ranges, they are disease claims.

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, such as diabetes and

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hypertension. 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, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

Please contact us if we may be of further assistance.

Sincerely yours,



Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
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-310
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Seattle District Office, Office of Compliance, HFR-PA340

RKS Inc.
6306 - 215th St. Southwest
Mountlake Terrace, Washington 98043
February 7, 2006

FEB 28 2006

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

Greetings:

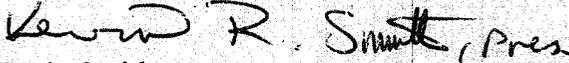
Notice is hereby given pursuant to Section 403(r)(6) (21 U.S.C. § 343(r)(6)) of the Federal Food, Drug and Cosmetic Act that RKS Inc. located at 6306 215th Street Southwest, Mountlake Terrace, Washington, 98043 intends to market dietary supplements known as LifeMag and Magnesium Plus under the Premium Nutrition brand name, bearing the following statement on the label and/or in the labeling:

Magnesium helps to maintain healthy:

- Menstrual cycle
- Bowel regularity
- Sleep quality
- Emotional balance
- Relaxation
- Blood sugar levels
- Kidneys
- Resistance to occasional stress
- Circulation
- Blood pressure
- Respiration (breathing)
- Resistance to excessive noise
- Heart health
- Bones

The undersigned certifies that the information contained in this notice is complete and accurate and that R.K.S. Inc. has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,


Kevin Smith
President, RKS Inc.

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