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JUN - 7 2001

Ms. Susan Carlson
Vice President
J. R. Carlson Laboratories, Inc.
15 College
Arlington Heights, Illinois 60004-1985

Dear Ms. Carlson:

This is in response to your letters of May 15, 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 J. R. Carlson Laboratories, Inc. is making the following claims, among others, for the following products:

Potassium

"...regulating...blood pressure"

Pantothenic Acid

"...necessary for...synthesis [sic] of important biochemicals such as...antibodies."

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, cure or mitigate diseases, namely hypertension and infectious diseases. 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.


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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, Chicago District Office, Office of Compliance, HFR-MW140

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-810

HFS-811 (file)

HFD-310

HFD-314 (Aronson)

HFS-605

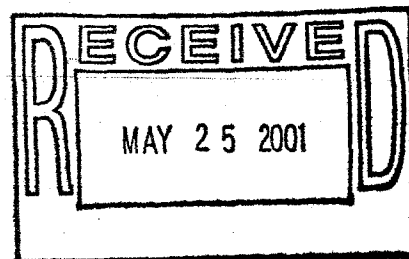
HFV-228 (Benz)

GCF-1 (Nickerson)

f/t:HFS-811:rjm:6/5/01:docname:76119.adv:disc56

Carlson[®]

May 15, 2001



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

Dear Sir or Madam:

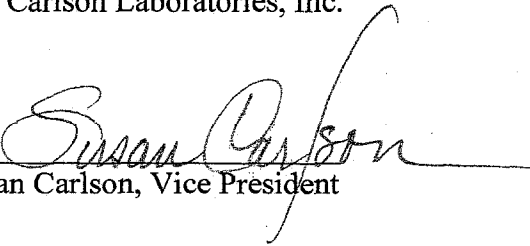
I hereby notify the Food and Drug Administration (FDA) of the use of a statement of nutritional support in the labeling of Carlson Potassium. Carlson Division of J. R. Carlson Laboratories, Inc., Arlington Heights, Illinois 60004, is the distributor of Carlson Potassium.

Statement being made in the labeling of the above mentioned Carlson product:

“Potassium is an essential mineral playing important roles in many body functions, such as regulating water balance, heart rate, blood pressure, muscular contraction, nerve impulse conduction, hormone and enzyme systems, bone growth, and detoxification.”

To the best of my knowledge, and based upon information and belief present at the time of the executing of the notice, I certify that the above information is accurate and complete; and the J.R. Carlson Laboratories, Inc. possesses substantiation that the statements are truthful and not misleading.

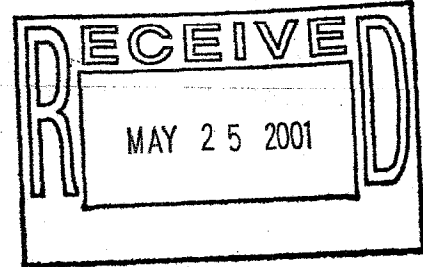
J.R. Carlson Laboratories, Inc.

By 
Susan Carlson, Vice President

76119

Carlson®

May 15, 2001



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

Dear Sir or Madam:

I hereby notify the Food and Drug Administration (FDA) of the use of a statement of nutritional support in the labeling of Carlson Pantothenic Acid. Carlson Division of J. R. Carlson Laboratories, Inc., Arlington Heights, Illinois 60004, is the distributor of Carlson Pantothenic Acid.

Statement being made in the labeling of the above mentioned Carlson products:

"Pantothenic Acid is an essential water-soluble B-Complex vitamin. It is used to form Coenzyme A, which is necessary for energy metabolism and synthesis of important biochemicals such as acetylcholine and antibodies."

To the best of my knowledge, and based upon information and belief present at the time of the executing of the notice, I certify that the above information is accurate and complete; and the J.R. Carlson Laboratories, Inc. possesses substantiation that the statements are truthful and not misleading.

J.R. Carlson Laboratories, Inc.

By Susan Carlson
Susan Carlson, Vice President

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