REGULATORY LETTER

December 22, 1987

Certified Mail - Return Receipt Requested

Mr. Wynslow E. Ohlsen, President
The Key Company
1313 W. Essex
Kirkwood, MO 63122

88-STL-006

Dear Mr. Ohlsen:

On December 1, 1987, an investigator from the St. Louis Branch office of the Food and Drug Administration collected labels for mineral salts of Orotic acid (Orotates) which you repackage and distribute. These articles "CAL-K" capsulets which contain calcium orotate, "CALCIUM OROTATE" capsules, "MAGNESIUM OROTATE" capsules, "ZINC OROTATE" capsules, and "POTASSIUM OROTATE" tablets are in serious violation of the Federal Food, Drug, and Cosmetic Act as follows:

Section	Brief Description
402(a)(2)(C)	The articles CAL-K, calcium orotate, magnesium orotate, zinc orotate, and potassium orotate tablets, are or contain unsafe food additives within the meaning of Section 409, because there are no regulations in effect pursuant to Section 409 prescribing the conditions under which these additives may be safely used and there is no exemption in effect for such use pursuant to Section 409.
403(a)(1), 201(n)	The labels for the CAL-K products fail to reveal the material fact of what percentages of the U.S. RDA of calcium and vitamin D are present.
403(a)(1)	The following label statements on the CAL-K products are false and misleading: 100 CAL-K "The RDA of Calcium is 2000 mg." (1000 CAL-K and CAL-K 100 capsulets)" R.D.A. = U.S. recommended daily allowance."
403(e)(1)	The label for CAL-K 100 capsulets fails to bear a complete statement of the place of business of the distributor in that the state and zip code are not declared.
403(e)(2) FPLA Sec 4 (a)(2)	The label of 1000 CAL-K fails to bear an accurate net quantity of contents statement.

For your information, in U.S. v. Article of food . . . Orotic Acid, 414 F. Supp. 793 (E.D. Mo. 1976), the U.S. District Court, in its judgment, included Findings of Fact, which stated "Orotic Acids and its salts are not

generally recognized among experts qualified by scientific training and experience to evaluate its safety as having been adequately shown through scientific procedures or experience based on common use in food to be safe under conditions of intended use." Therefore, orotic acid and its salts are food additives and illegal (unsafe) food additives since there are no food additive regulations in effect which provide for their safe use.

Please be advised that continued distribution of the adulterated articles is a violation of the Federal Food, Drug, and Cosmetic Act.

We request that you respond, in writing, within ten (10) days of receipt of this letter of the action you will take to stop the repacking and marketing of the illegal food additives and misbranded dietary supplements. If such action is not taken, the Food and Drug Administration is prepared to invoke regulatory sanctions such as seizure and/or injunction.

For your further information, the terms "Dosage", "indications" and "Contraindications" used on the CAL-K product are not appropriate for use on food products and should be deleted from the labels. We would not object to a "Directions for Use" statement.

Vitamin D should be expressed in terms of International Units.

Your response should be directed to Spencer L. Sorenson, Compliance Officer, at the address referenced in the letterhead.

Sincerely,

Raymond K. Bedblad
Director
St. Louis Branch

RKH/SLS/sp

bcc: HFA-224; JAA; F/J; S/J; SLS; R/F; HFF-314; HFW-35; FSIS