



Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, Maryland 20740

DEC 10 2004

Mr. Dini Philip  
Sales Manager  
MTC Industries, Inc.  
299 East Shore Road, Suite 207  
Great Neck, NY 11023

Dear Mr. Philip:

This is to inform you that the notification you submitted, dated September 27, 2004, pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on September 28, 2004. Your notification concerns the substance called "L-Arginine alpha-ketoglutarate (2:1)" that you intend to market as a new dietary ingredient.

The notification informs FDA that MTC Industries, Inc. intends to distribute the new dietary ingredient, "L-Arginine alpha-ketoglutarate (2:1)" in 1000 mg tablets manufactured by Molecules Technology (Nantong) Co. Ltd. of Nantong City, China. The notification states that the suggested use will be for adult men to "Take 2 tablets once in the morning before breakfast and 2 tablets in the afternoon on an empty stomach....Do not use if under 18 years of age." The notification further contains a chart of suggested serving levels for men and women of various weights. The daily serving levels suggested in the chart in the notification range from 2 tablets per day for women under 125 lbs to 8 tablets a day for men over 200 lbs. The notification further contains suggestions to "Drink at least 64 ounces of water daily.", "Maintain your carbohydrate intake above 40% of your total daily caloric intake.", "Do not consume foods at least 30 minutes before or 30 minutes after taking this supplement" and "Do not take servings after 3:00 PM. Although this supplement contains no stimulants of any kind, it may keep you awake."

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement that contains a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety

establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is deemed to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

It is not readily apparent whether the "L-Arginine alpha-ketoglutarate (2:1)" that is the subject of your notification is a "dietary ingredient" within the meaning of 21 U.S.C. 321(ff)(1) that may be lawfully used in dietary supplements. The term "dietary supplement" is defined in 21 U.S.C. 321(ff). A dietary supplement means, among other things, a "product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

- (A) a vitamin;
- (B) a mineral;
- (C) an herb or other botanical;
- (D) an amino acid;
- (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
- (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E)."

In a communication to FDA on October 18, 2004, you asserted that "L-Arginine alpha-ketoglutarate (2:1)" is a dietary ingredient because it is an amino acid within the meaning of 21 U.S.C. 321(ff)(1)(D). However, your communication does not explain the basis upon which you have relied to reach that conclusion. Therefore, notwithstanding the discussion below of the information you rely upon as evidence that your product is reasonably expected to be safe, FDA remains unclear whether L-Arginine alpha-ketoglutarate (2:1) is a dietary ingredient that may lawfully be marketed as a dietary supplement.

Nevertheless, FDA has carefully evaluated the information in your submission and the agency has significant concerns about the evidence upon which you rely to support your conclusion that "L-Arginine alpha-ketoglutarate (2:1)" when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe.

FDA was unable to determine the identity of your new dietary ingredient, "L-Arginine alpha-ketoglutarate (2:1)". Your notification contained references to L-Arginine, L-Arginine alpha-ketoglutarate (1:1) and L-Arginine alpha-ketoglutarate (2:1). FDA was unable to determine the identity of your new dietary ingredient using the "Flow Chart of L-Arginine AKG: MANUFACTURING AND PROCESSING", the "IDENTITY TESTING BY IR", the "HPLC REPORT" and the other statements enclosed with your notification.

Moreover, your notification included printed material and reprints from web sites discussing supplementation with arginine as well as promotional material for what appear to be dietary supplement products. The ingredients of these other products are not clearly described. It is not clear to FDA that any of them contain "L-Arginine alpha-ketoglutarate (2:1)" and some of them clearly contain additional or different ingredients. Therefore, it is not evident that the products

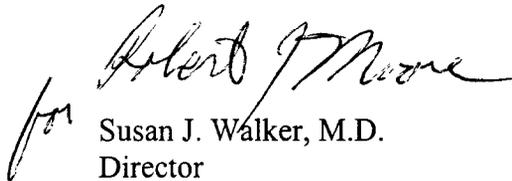
described in these materials are qualitatively or quantitatively similar to your "L-Arginine alpha-ketoglutarate (2:1)" or how these materials are relevant to evaluating the safe use of your new dietary ingredient under the recommended conditions of use.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that "L-Arginine alpha-ketoglutarate (2:1)", when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your product may be adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Your notification will be kept confidential for 90 days after the filing date of September 28, 2004. After the 90-day date, the notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter, please contact Linda Pellicore, Ph.D. at (301) 436-2375.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan J. Walker". The signature is written in a cursive style and is positioned to the left of the typed name.

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