

APPENDIX 16



DEPARTMENT OF HEALTH & HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Public Health Service

Memorandum

Date .APR - 6 1998

From Senior Regulatory Scientist, Regulatory Branch, Division of Programs & Enforcement Policy (DPEP), Office of Special Nutritionals, HFS-456433 '98 APR -9 P2:07

Subject 75-day Premarket Notification for New Dietary Ingredient

To Dockets Management Branch, HFA-305

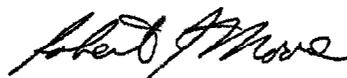
New Dietary Ingredient: Creatine-pyruvate

Firm: SKW Trostberg AG

Date Received by FDA: March 31, 1998

90-day Date: June 28, 1998

In accordance with the requirements of section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification for the aforementioned new dietary ingredient should be placed on public display in docket number 95S-0316 after June 28, 1998.


Robert J. Moore, Ph.D.

95S-0316

RPT 28



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

APR - 6² 1998 4 '98 APR -9 P2:07

Robert B. Nicholas, Esq.
McDermott, Will & Emery
600 13th Street, N.W.
Washington, D.C. 20005-3096

Dear Mr. Nicholas:

This is to notify you that your submission pursuant to section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act) dated March 27, 1998, on behalf of SKW Trostberg AG, concerning the marketing of a substance that you assert is a new dietary ingredient (i.e., creatine-pyruvate) was received by the Food and Drug Administration (FDA) on March 31, 1998. Your submission will be kept confidential for 90 days from the date of receipt, and after June 28, 1998, your submission will be placed on public display at Dockets Management Branch (Docket No. 95S-0316). Commercial and confidential information in the notification will not be made available to the public.

Please contact us if you have questions concerning this matter.

Sincerely,

A handwritten signature in cursive script that reads "Robert J. Moore".

Robert J. Moore, Ph.D.
Senior Regulatory Scientist
Division of Programs and Enforcement Policy
Office of Special Nutritionals

580977

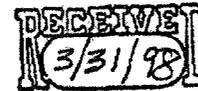
A Partnership Including
Professional Corporations
600 13th Street, N.W.
Washington, D.C. 20005-3096
202-756-8000
Facsimile 202-756-8087
http://www.mwe.com

Boston
Chicago
Los Angeles
Miami
Moscow
Newport Beach
New York
St. Petersburg
Silicon Valley
Vilnius
Washington, D.C.

Robert B. Nicholas
Attorney at Law
rnicholas@mwe.com
202-756-8170

MCDERMOTT, WILL & EMERY

March 27, 1998



BY MESSENGER

Office of Special Nutritionals (HSF-450)
Center For Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street S.W.
Washington, DC 20204

Re: Premarket Notification of New Dietary Ingredient Creatine Pyruvate

Dear Sir:

On behalf of our client SKW Trostberg AG ("SKW") notice is hereby given pursuant to the requirements of Section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 350b) of the intent of SKW to introduce into interstate commerce in 75 days herefrom a new dietary ingredient, creatine pyruvate. In accordance with 21 CFR § 190.6 the following information is provided:

1. Manufacture:

SKW Trostberg AG
P.O. Box 1262
D-83303 Trostberg
GERMANY

2. New Dietary Ingredient:

Creatine Pyruvate

3. Dietary Supplement:

- (i) The new ingredient contains pure pyruvic acid molecularly bonded to pure creatine, in a 40 to 60 percent ratio.
- (ii) The new dietary supplement is composed of 100% creatine pyruvate;

- (iii) The recommended condition for use is 5-10 grams/day taken in 2 equal doses, mixed with a beverage.
4. SKW has concluded that the dietary supplement containing the new dietary ingredient will reasonably be expected to be safe under the recommended conditions of use based on numerous studies and other information, including the following documents, copies of which are appended hereto:
- (i) THE NUTRITIONAL BIOCHEMISTRY OF CREATINE, PAUL L. GREENHAFF, Nutritional Biochemistry 1997, 8:610-618;
 - (ii) CREATINE SUPPLEMENTATION IN HUMANS, PAUL D. BALSOM, The Clinical Pharmacology of Sport and Exercise, 1997, 167-177;
 - (iii) CREATINE IN HUMANS WITH SPECIAL REFERENCE TO CREATINE SUPPLEMENTATION, PAUL D. BALSOM, Karin Soderlund and Bjorn Ekblom - Karolinska Institute, Department of Physiology and Pharmacology, Physiology 111, and University College of Physical Education and Sports, Stoekholm, Sweden, Sports Med. 18(4) 268-280, 1994;
 - (iv) CREATINE SUPPLEMENTATION ENHANCES MUSCULAR PERFORMANCE DURING HIGH-INTENSITY RESISTANCE EXERCISE, JEFF S. VOLEK ET AL, J. Am. Diet. Assoc. 1997, 97(7), 756-770;
 - (v) ENHANCEMENT OF ARM-EXERCISE ENDURANCE CAPACITY WITH DIHYDROXY-ACETONE AND PYRUVATE, STANKO, R.T., Robertson, R.J., Spina, R.J., Reilly, J.J., Greenawalt, K.D., Goss, F.L., Journal of Applied Physiology 68:119-124, 1990;
 - (vi) BODY COMPOSITION, ENERGY UTILIZATION, AND NITROGEN METABOLISM WITH A 4.25-MJ/D LOW-ENERGY DIET SUPPLEMENT WITH PYRUVATE STANKO, R.T., Tietze, D.L., Arch, J.E., American Journal of Clinical Nutrition 56:630-635. 1992;
 - (vii) BODY COMPOSITION, ENERGY UTILIZATION AND NITROGEN METABOLISM WITH A SEVERELY RESTRICTED DIET SUPPLEMENTED WITH DIHYDROXYACETONE AND PYRUVATE STANKO, R.T., Tietze, D.L., Arch, J.E., American Journal of Clinical Nutrition 55:771-775. 1992;

Office of Special Nutritionals (HSF-450)
March 27, 1998
Page 3

(viii) REFERENCE OF CREATINE PYRUVATE AND ITS
APPLICATION AS A DIETARY INGREDIENT OR
DIETARY SUPPLEMENT, Paradics, H.H. 2-2-98.

Please direct all correspondence regarding this matter to the undersigned. Please feel free to call me if you have any questions.

Sincerely,



For SKW Trostberg AG
Robert B. Nicholas, Esq.
Outside Regulatory Counsel

Enclosures

cc: SKW Trostberg AG

144709\011\80FDANOT.001