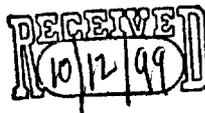


1824 South Robertson Blvd.
Los Angeles, CA 90035-4317
310/204-6936 • 800/726-0886
October 5, 1999

Fax Numbers
Orders 800/890-8955
General 310/204-2520
Administrative 310/204-5132

1 2 0 4 '99 OCT 27 11:24

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



67605

Dear Sir or Madam:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

(1) Name and address of distributor:

Jarrow Formulas, 1824 South Robertson Blvd., Los Angeles, CA 90035

(2) Text of the statement(s):

SAM-e 200: S-Adenosyl Methionine. 200 mg elemental SAM-e

- Joint Strength
- Mood and Brain Function
- Liver Detoxification
- Longevity

SAM-e (S-Adenosylmethionine) is an amino acid derivative that has been clinically proven to benefit brain and joint function. Found in all living cells, SAM-e is also called "activated" methionine (an essential amino acid) since it is formed by the combining of ATP with methionine. SAM-e has undergone dozens of trials involving thousands of patients. Researchers studying the beneficial effects of SAM-e have identified the following benefits of SAM-e:

Joint Strength: SAM-e supports the production of healthy connective tissue through transulfuration. In this process, critical components of connective tissue, including glucosamine and the chondroitin sulfates, are sulfated by SAM-e metabolites.

Brain Metabolism: SAM-e methylation reactions are involved in the synthesis of neurotransmitters such as L-dopa, dopamine and related hormones, epinephrine and phosphatidylcholine (a component of lecithin).

Liver: SAM-e metabolism supports the synthesis of glutathione (GSH) and glutathione-dependent enzymes (glutathione peroxidase and glutathione-S-transferase), which are substances important for liver function.

Longevity: Methylation of DNA appears to be important in the suppression of errors in DNA replication. Demethylation of DNA is considered a contributor to the aging process. Proper methylation through substances such as SAM-e positively influences longevity.

LET 4505

SAM-e 200 Insert: SAM-e (S-Adenosylmethionine) is an amino acid derivative that has been clinically proven to benefit brain and joint function. Found in all living cells, SAM-e is also called "activated methionine" (an essential amino acid) since it is formed by the

combination of ATP to methionine. However, supplementation with simply methionine does not result in SAM-e elevation, and, in fact, can cause elevation of toxic homocysteine. SAM-e has undergone dozens of clinical trials involving thousands of patients. Researchers studying the beneficial effects of SAM-e have identified the following structure and function benefits of SAM-e:

SAM-e supports the production of healthy connective tissue through a process of transulfuration. In this process, critical components of connective tissue, including glucosamine and the chondroitin sulfates, are sulfated by SAM-e metabolites. SAM-e also increases the production of methyl-thio-adenosine, an intermediate that reduces inflammation which may partially account for the joint benefits of SAM-e. The metabolism of SAM-e also results in the production of L-cysteine, an important amino acid used by the body to construct a family of sulfur-containing compounds of critical importance including glutathione. Some of these compounds are the building blocks needed for the synthesis of cartilage, ligaments, tendons, and the bone matrix.

SAM-e metabolism supports the synthesis of glutathione (GSH) and glutathione-dependent enzymes (glutathione peroxidase and glutathione-S-transferase), which are substances important for liver function. Glutathione is necessary for the scavenging of free radicals produced by glycolysis, the breakdown of carbohydrates for energy. The amino acid taurine is another endproduct of SAM-e metabolism. The glutathione family of compounds and taurine are important for liver detoxification reactions.

Methylation and Brain Metabolism: SAM-e supports brain function by its methylation effects. Methylation is the process by which a four atom appendage (unit of one carbon and three hydrogen atoms) is transferred from one molecule to another. Of all methyl-donating substances known in mammalian metabolism, SAM-e is the most important. The donation of methyl groups affects the proper function of many metabolic processes including brain function, energy production and DNA metabolism. Neurotransmitters, substances involved in the brain's cell-to-cell communication, are the products of methylation reactions. These compounds include L-dopa, dopamine and related hormones, epinephrine and phosphatidylcholine (a component of lecithin).

Methylation from SAM-e is critical for proper energy production as it converts guanidinoacetate to creatine. Creatine metabolizes to creatine phosphate, which is important for the recycling of ADP to ATP. Creatine maximizes physical performance, reduces exercise fatigue and improves recovery after exercise. Methylation of DNA appears to be important in the prevention of DNA imperfections. The demethylation of DNA is considered a contributor to the aging process. Proper methylation through substances such as SAM-e positively influence longevity. Pharmacokinetic studies show that oral supplementation of SAM-e is most effective when enteric-coated by special gastric-resistance polymers. Enteric-coating SAM-e results in maximum SAM-e levels in the bloodstream.

(3) Name of the dietary ingredient if not provided in the text of the statement:

S-Adenosyl methionine (see above)

(4) Name of the dietary supplement

SAM-e 200

(5) The following disclaimer appears on the label: These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

These claims are limited to, and a result of, what we believe to be a substantial body of scientific evidence supporting the functional role of these nutrients. A compendium of relative published research substantiating the above statement(s) is on file at the corporate office.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Siddharth Shastri', with a stylized flourish at the end.

Siddharth Shastri

Director of Product Development