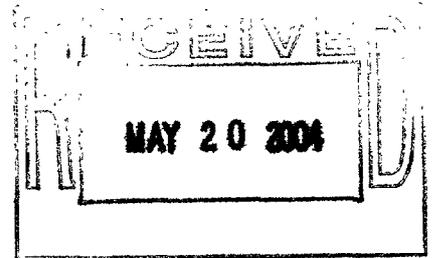




May 14, 2004



Dr. Robert Moore
Division of Compliance and Enforcement/ONPLDS
Center for Food and Safety and Applied Nutrition
U.S. Food and Drug Administration
HFS – 810
5100 Paint Branch Parkway
College Park, MD 20740

Dear Dr. Moore:

Inverness Medical Nutritionals Group has launched a new dietary supplement and wishes to notify the Food and Drug Administration. The supplement, *SAM-e*, (S-adenosylmethionine Tosylate Disulfate) 200 mg (also in 400 mg), will bear the following structure/function statements on the label(s).

Display Panel (Box)

Mood SUPPORT *
Joint COMFORT*
Liver HEALTH*

Side Panel (Box)

SAM-e (S-adenosylmethionine) is natural compound found in all living organisms *SAM-e* is distributed throughout the human body and plays significant roles in many biochemical processes including mood and emotional support, joint comfort, and liver health. *SAM-e* is not easily available from typical dietary sources; the body must produce its own. As the body ages the amount of *SAM-e* produced declines so supplementation is important.

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Also, certain groups of people tend to have lower amounts of this important ingredient in their systems. It is important to sustain proper levels of SAM-e in the body. SAM-e supplements have been demonstrated to benefit many including those in need of:

Mood and Emotional Support by its effect on maintaining a balance of neurotransmitters necessary for healthy brain function.

Joint Comfort by maintaining joint cartilage health, which naturally deteriorates with physical activity and age.

Liver Health by helping maintain healthy liver activity.

SAM-e has been proven safe and non-toxic for short and long-term use. Its effectiveness after decades of research has been well-documented in respected medical journals.

SAM-e is a safe and effective product that can benefit you!

*** 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.**

Insert [See attached for product insert text]

We certify that the information contained in this notice is complete and accurate, and we have substantiation that the above structure/function statements are truthful and not misleading.

Sincerely,



William J. Neumann
Vice President
Quality and Regulatory Affairs

SAFETY AND INTERACTIONS

One of the advantages of SAM-e over other compounds is its remarkable safety profile. For over 20 years SAM-e has been safely and successfully used. SAM-e is supported by dozens of clinical studies involving thousands of people.

People that currently take prescription antidepressants should consult their doctor before taking SAM-e.

Individuals with bipolar (manic) depression should only take SAM-e under the supervision of their physician.

If you are pregnant or nursing a baby, seek the advice of a health professional before using this product.

SAM-e

(S-adenosylmethionine)
Enteric Coated Tablets

ABOUT SAM-e

Thank you for your recent purchase of SAM-e. We are confident that you will be satisfied with our product. This package insert contains important information about SAM-e that will help you understand and take full advantage of the many benefits that SAM-e offers.

National magazines, newspapers, and primetime TV shows have all featured stories of SAM-e's benefits to support and promote liver health, joint health and mobility, joint comfort, and mood and emotional well-being.* All this, with reports of little or no side effects.

WHAT IS SAM-e?

SAM-e (S-adenosylmethionine) has been used in Europe for over 20 years and is beginning to establish its presence in the U.S. market. SAM-e is not an herb or a hormone. It's a compound that all living cells provide constantly and takes part in several biochemical reactions in the human body.

BENEFITS OF SAM-e

SAM-e is a naturally occurring compound present in all living organisms. In humans SAM-e is distributed throughout the body and is involved in many important biochemical reactions. The important physiological results of these reactions are the manufacture of joint cartilage and the maintenance of neural cell membrane function.*

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SOURCES OF SAM-e

Although SAM-e is present in all living organisms, significant amounts of the substance are not readily available through foods. The production of SAM-e involves the cultivation of a special SAM-e producing yeast, the subsequent collection of SAM-e from the yeast, and the integration of SAM-e into a stable compound. The resulting compound is then put into a specially formulated and enteric coated tablet to further enhance stability, provide release of SAM-e in the intestinal tract where it is best absorbed, and increase ease of swallowing.

SUGGESTED USE

For optimal absorption into the body, the best time to take SAM-e is on an empty stomach at least 30 minutes before a meal. Taking SAM-e at bedtime may interfere with a good night's rest.

Regular Strength 200 mg tablets, take 2 tablets once a day.

Double Strength 400 mg tablets, take 1 tablet daily.

Clinical studies indicate that benefits may be evident in the first week or two of supplementation and may continue for a prolonged period of time. SAM-e can be used regardless of the number of benefits that are being sought. *

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STUDIES

Top institutions such as Harvard Medical School, Massachusetts General Hospital, University of California Medical Center, and London's Kings College Hospital have evaluated SAM-e and published results in respected medical journals such as The American Journal of Medicine.

SAM-e has been studied extensively and has been clinically found to support and promote:

- **Joint Health, Mobility, and Joint Comfort***
- **Mood and Emotional Well-Being***
- **Liver Health***

WHO IS LIKELY TO BE DEFICIENT

As people age it becomes more and more important to supplement your diet with SAM-e. Because significant levels of SAM-e are not readily available through the diet, groups of people, including the elderly, have low levels of SAM-e in their bodies. Since our diets don't provide a sufficient amount of SAM-e, it's important to make sure you get an adequate amount of SAM-e by way of supplementation.

Adequate levels of vitamins B-6, B-12, and Folic Acid are necessary for the synthesis of SAM-e, ask your pharmacist or physician if they would recommend a multivitamin.

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