DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

NOV 14 1997

Mr. Dave Brown
US Botanicals
1611 N. Sawyer
Mesa, Arizona 85207

Dear Mr. Brown:

This is in response to your letter of October 14, 1997 to the Food and Drug Administration (FDA) pursuant to section 413 of the Federal Food, Drug, and Cosmetic Act (the act) concerning the marketing of S-adenosylmethionine (SAM) as a new dietary ingredient.

Section 413 of the act requires a manufacturer or distributor of a dietary supplement which contains a new dietary ingredient to submit certain information to the agency. Specifically, the act requires that at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient provide the FDA with information which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe. Because you submitted to FDA information which is the basis on which you concluded that the dietary supplement will reasonably be expected to be safe, the agency will consider your submission to be the required 75-day premarket notification of your intent to sell SAM as a dietary supplement. As required by section 413(a)(2) of the act, we will keep your submission confidential for 90 days from the date of receipt, and on January 20, 1998, it will be placed on public display at Dockets Management Branch. Commercial and confidential information in the notification will not be made available to the public.

Be advised that there is no requirement that dietary supplements be approved by the FDA prior to marketing. It is the responsibility of the person who introduces a dietary supplement into interstate commerce to ensure that the dietary supplement is safe for its intended use and is properly labeled.

Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

955-0316

RPT 19

DEPARTMENT OF HEALTH & HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Public Health Service

Memorandum

Date NOV 14 1997

From Acting Director, Division of Programs & Enforcement Policy, Office of Special Nutritionals, HFS-455

Subject 75-day Premarket Notification for New Dietary Ingredients

To Dockets Management Branch, HFA-305

New Dietary Ingredient:	S-adenosylmethionine
Firm:	US Botanicals 1611 N. Sawyer Mesa, AZ 85207
Date Received by FDA:	October 21, 1997
90-Day Date:	January 20, 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 January 20, 1998.

James T. Tanner, Ph.D.

Attachment

cc:
HFS-22 (CCO)
HFS-450 (w/cpy incoming, OSN#55315, r/f)
HFS-456 (File)
f/t:HFS-456:rjm:11/12/97:DocName:55315.MEM:disc24

US Botanicals
1611 N. Sawyer
Mesa, AZ 85207
Phone: (602) 641-8209
FAX: (602) 838-8283

Food And Drug Administration
Office of Special Nutritionals
200 C Street SW
Washington DC, 20204

Tuesday, October 14, 1997

To whom it concerns:

Enclosed is information on the safety of a new dietary supplement we plan to market (S-adenosylmethionine). Although the information is compiled from clinical trial data, it is not provided to claim efficacy of our product, only safety. We plan to market a daily oral dose of 1,200 mg, which is identical to the level used in one of the clinical trials involving over 200 subjects, and at which dose there was no difference between S-adenosylmethionine and placebo in the number of side effects. In all the enclosed journal articles the relevant information on tolerability is circled or underlined.

Thank you for your time evaluating this information. I will be glad to speak with anyone at FDA about any opposition to or basic concerns about this product.

Sincerely,

Dave Brown

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