



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service  
Food and Drug Administration  
d1471b

Dallas District  
3310 Live Oak Street  
Dallas, Texas 75204-6191

March 6, 1998

**Ref: 98-DAL-WL-24**

**WARNING LETTER**

**VIA FEDERAL EXPRESS**

Ms. Patricia K. Rodes, President  
Stevita Co., Inc.  
7650 Highway 287, Suite 100  
Arlington, TX 76017

Dear Ms. Rodes:

During an inspection of your facility on the dates of October 30 and November 12, 1997, Food and Drug Administration (FDA) investigators documented violations of the Federal Food Drug and Cosmetic Act (the Act). Your Stevita Stevia products labeled as Dietary Supplements are actively promoted, through labeling in the form of promotional literature, as conventional foods. FDA has confirmed the presence of stevia in your products by laboratory analysis. When used as an ingredient of a food, or when offered and intended as conventional food, stevia is considered a food additive. Stevia is an unapproved food additive, rendering your products unsafe within the meaning of Section 409 of the Act, and hence adulterated within the meaning of Section 402(a)(2)(C) of the Act.

There is no regulation in effect which provides conditions for the safe use of stevia. Neither is there an exemption [Generally Recognized as Safe (GRAS), or prior sanction] in effect which excludes stevia from the need for a regulation. The available toxicology information on stevia is inadequate to demonstrate the safety of the substance. As a result significant safety concerns exist for the general use of stevia.

Labeling your stevia products as Dietary Supplements does not necessarily make the products dietary supplements as provided for under the Act. Under the Dietary Supplement Health and Education Act of 1994, the definition of a dietary supplement does not include products represented for use as conventional foods

The agency has reviewed your product labeling and promotional literature provided during the inspection by Mr. Oscar D. Rodes, Vice President of Operations. Additionally, we have reviewed other promotional material and a Stevita cookbook promoting the use of your

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stevia products at the retail marketing level. Your Stevita Stevia products are promoted in colored promotional literature which depicts such products as stevia liquid, stevia blend (maltodextrin and stevia) in jars and packets, and flavored drink blends (powdered cocoa, milk, and or coffee and stevia) , as foods, conventional foods, or components of foods. Additionally, this literature pictures a drink appearing to be coffee or tea surrounded by jars and packets of Stevita Stevia. This promotional effect depicts a sweetening agent as a table top sweetener (a conventional food).

This literature makes the following statements of benefits for the products: "\*\*\*\* some of the benefits of this health supplement are: flavor enhancer, non-caloric, heat stable, anti-cavity promoter, and healthful.\*\*\*\*"

A second piece of colored promotional literature, found to be displayed with your products at the retail level, makes the following statements and claims for your Stevita stevia which further establishes the intended use of the product as a tabletop sweetener and a substitute for sugar: "\*\*\*\* Stevita \*\*\*Stevia \*\*\* HOW IS IT USED? \*\*\* as a diet supplement to help regulate blood sugar level. \*\*\* In its pure form, the stevia extract is 200 to 300 times sweeter than sugar - but it is not sugar! \*\*\* Just use it right out of the jar.\*\*\*\*"

A review of the container labeling for 50/1g packets of Stevita Stevia finds the product labeled as "\*\*\*\* tabletop ready. \*\*\* Just use it straight out the packets. \*\*\*\*"

Investigators identified other means by which your firm represents Stevita stevia products as conventional foods. The distribution of promotional literature and your cookbook (STEVITA Select recipes from Stevita) offered for sale at retail establishments displaying your products, is also supplemented by your firm's Internet Web Site.

Your firm was previously provided official FDA warning of the unapproved food additive status of stevia in the form of a Seizure action in U.S.A. vs. Diet Teas Steviasweet, Civil No. 4-91-406-E in the United States District Court for the Northern District of Texas, Fort Worth Division, filed June 6, 1991.

You should notify this office in writing, within 15 working days of receipt of this letter, of the steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations in the promotion and distribution of your products. Failure to correct the violations may result in further regulatory action without further notice. These regulatory actions may be in the form of additional product seizures or injunctive action against your firm and responsible individuals.

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If corrective action cannot be completed within 15 working days, state the reason for the delay and the time period within which corrections will be completed. Please direct your response to James R. Lahar, Compliance Officer at the above address.

Sincerely,



Joseph R. Baca  
Dallas District Director

JRB:JRL