



DEPARTMENT OF HEALTH & HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Public Health Service

Memorandum

Date . SEP 25 1995

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

Subject Submission for Docket 95S-0316, 75-Day Premarket Notifications for New Dietary
Ingredients

To Jennie Butler, HFA-305
Dockets Management Branch

Firm: Sunrider Corporation, W. Patrick Noonan, counsel

Please place the attached 75-day notification for stevia from Sunrider Corporation, on public display in the docket 95S-0316, on October 4, 1995.

If you have any questions, please call me at (202) 205-4168. Thank you.

Linda S. Kahl, Ph.D.

DOCKET MANAGEMENT
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AUG 16 1995

W. Patrick Noonan
Warner Center Plaza, Suite 840
21800 Oxnard Street
Woodland Hills, California 91367

Dear Mr. Noonan:

This is in response to your April 17, 1995, letter to Dr. Elizabeth Yetley, received on July 7, 1995, requesting that FDA either agree that *Stevia rebaudiana* Bertoni (stevia) is an "old" dietary ingredient for use in dietary supplements, or that FDA consider your submission as the required 75-day premarket notification of intent by your client (Sunrider) to sell stevia as a new dietary ingredient. You asked that FDA issue a written response outlining the agency's concurrence or objections to the legal positions presented.

In order to evaluate your first position that stevia is an "old" dietary ingredient, we must first evaluate the intended use of this product, i.e., whether it will be used as a dietary ingredient in a dietary supplement, or whether it will be used as a component of conventional food or as conventional food. As you are aware, ingredients may be marketed as components of conventional foods or as conventional foods if they are generally recognized as safe (GRAS) for their intended use or are used in accordance with a food additive regulation that specifies the conditions under which the additives may be used safely. Stevia is not listed as a food additive nor listed or affirmed as GRAS. In fact, in 1984, FDA initiated a judicial seizure action against various stevia products marketed by Sunrider on the grounds that they contained an unapproved food additive, stevia. Sunrider entered into a consent decree that prohibited it from selling products containing stevia.

If your client's intended use of stevia is as a component of conventional foods or as conventional food, then stevia would remain an unlisted, and therefore unsafe, food additive. Without reviewing product labeling, it is unclear from your submission how the stevia is to be used. However, paragraph 3 on page 1 of your cover letter mentions "use as a dietary ingredient in herbal tea." Teas, including herbal teas, are conventional foods (beverages), and therefore, their ingredients are not dietary ingredients under the Federal Food, Drug, and Cosmetic Act (the act) (see section 201(ff) (21 U.S.C. 321(ff)). In addition, FDA would consider stevia as an unsafe food additive if the substance is used in a food, including a dietary supplement, for a technical effect, such as use as a sweetener or flavoring agent. However, use of stevia as a dietary ingredient in a dietary supplement is not subject to the food additive provisions of the act.

Page 2 - Mr. Noonan

Your submission presents evidence of the marketing of stevia in a dietary supplement before October 15, 1994. However, FDA interprets section 413(c) of the act, which defines a "new" dietary ingredient as a dietary ingredient that was not marketed before that date, to mean a dietary ingredient that was not lawfully marketed before that date. The fact that Sunrider entered into a consent decree that prohibited it from selling products, including dietary supplements, containing stevia demonstrates that this ingredient was not lawfully marketed before October 15, 1994, and the passage of the Dietary Supplement Health and Education Act. Thus, stevia, when used as a dietary ingredient of a dietary supplement, is a "new" dietary ingredient. The agency is accepting your submission as the required 75-day premarket notification of your client's intent to sell stevia as a new dietary ingredient. That notification period expires on September 19, 1995. As required by section 413(a)(2) of the act, we will keep your submission confidential for 90 days from date of receipt, and thus on October 4, 1995, it will be placed on public display.

Nevertheless, you should be aware of the agency's continued concern over the safety of stevia. We note that there are several published scientific studies suggesting that the consumption of aqueous extracts of stevia reduces the fertility of female laboratory animals. Additionally, other published studies raise concern over the possible hypoglycemic (low blood sugar level) effect of stevia in human subjects. These concerns are currently unresolved.

If you have any questions, please do not hesitate to contact us.

Sincerely yours,

Linda S. Kahl, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

JUL 7 1995

W. Patrick Noonan
Warner Center Plaza, Suite 840
21800 Oxnard Street
Woodland Hills, California 91367

Dear Mr. Noonan:

This is to acknowledge receipt on July 7, 1995, of your cover letter of April 17, 1995, to Dr. Elizabeth Yetley, requesting an opinion from FDA that the agency agrees that Stevia is a legally recognized dietary ingredient that can be imported as a "grandfathered" or "old" dietary ingredient for use in dietary supplements. In addition, you alternatively request that FDA accept your letter as the required 75-day notification to the agency of your client's intent to introduce Stevia for sale as a new dietary ingredient in the United States. We understand you will send us additional material for our review next week.

Sincerely yours,

Linda S. Kahl, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
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and Applied Nutrition



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**CONFIDENTIAL ATTORNEY WORK PRODUCT
CONFIDENTIAL ATTORNEY/CLIENT COMMUNICATION**

July 7, 1995

Linda Kahl
Office of Special Nutritionals
U.S. Food & Drug Administration (HFF-455)
FB8, Room 2804
200 C Street SW
Washington, DC 20204

**RE: Stevia rebaudiana bertonii
Use as a Dietary Supplement Ingredient**

Dear Ms. Kahl:

At the request of Patrick Noonan, enclosed is the letter with attachments regarding use of Stevia rebaudiana bertonii as a dietary supplement ingredient. Please note that this letter was submitted on April 17, 1995, to Dr. Elizabeth A. Yetley, for consideration of stevia as a grandfathered or old dietary ingredient, or in the alternative, a 75-day notification of The Sunrider Corporation dba Sunrider International ("Sunrider")'s intent to market stevia.

Patrick Noonan will telephone you on Monday, July 10, 1995 to discuss this matter further.

Thank you for your assistance in this matter.

Very truly yours,

SUNRIDER INTERNATIONAL

Holly A. Vanderdonck

Holly A. Vanderdonck
Associate Counsel

HAV:ks

cc: Patrick Noonan, Esq. (w/out enclosures)

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RECEIVED BY THE
OFFICE OF SPECIAL
NUTRITIONALS, HFFS-450

LAW OFFICES

W. PATRICK NOONAN
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TELEPHONE (818) 887-8600
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April 17, 1995

VIA FEDERAL EXPRESS

Dr. Elizabeth A. Yetley, Acting Director
Office of Special Nutritionals
U.S. Food and Drug Administration (HFS-450)
FB8, Room 2804
200 C Street, S.W.
Washington, D.C. 20204

Re: Stevia Rebaudiana Bertoni
Use as a Dietary Supplement Ingredient

Dear Dr. Yetley:

We have been requested by The Sunrider Corporation, dba Sunrider International, Inc. ("Sunrider"), located at 1625 Abalone Avenue, Torrance, California 90501, to request the concurrence and acquiescence of the Food and Drug Administration (FDA) in the marketing of Stevia or Stevia Leaf (hereafter Stevia) as a safe and suitable dietary ingredient for use in dietary supplement products.

Sunrider considers it necessary to request FDA to provide written concurrence that the agency agrees with its legal position that Stevia can be imported for use as a dietary ingredient in dietary supplement products.

FDA has previously issued an Import Alert (45-06) that proscribes the importation of Stevia leaf because the agency considered it to be an unsafe food additive. With the passage of the Dietary Supplement Health and Education Act of 1994 (DSHEA), dietary supplements and their ingredients are deemed to be a food and legally cannot be regulated as unsafe food additives. In consideration of the provisions of this new legislation, Sunrider desires to import Stevia for use as a dietary ingredient in herbal tea and other herbal dietary supplements and as a single entity dietary supplement product.

Sunrider is aware that FDA has considerable discretionary enforcement in regulating imported products. Realizing the

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APR 19 1995

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significant financial expenditure required to import and market Stevia, Sunrider does not wish to engage in such investment if Stevia may be subject to an FDA import detention, resulting in protracted and expensive negotiations to determine its correct legal status. For that reason, Sunrider is requesting a written opinion from FDA that the agency agrees that Stevia, is a legally recognized dietary ingredient that can be imported as a "grandfathered" or "old" dietary ingredient for use in dietary supplements.

I. **BACKGROUND**

Sunrider was founded by Dr. Tei Fu Chen and began business in Orem, Utah in 1982. The company subsequently moved to Southern California in 1987, where it located its worldwide headquarters. Sunrider is a company that is dedicated to helping people achieve both health and prosperity through the sale of unique herbal formulas. Those products include, "Sunergy", a concentrated herb food program formulated to supplement a healthy diet, "Vitalite," an herbal weight management program and "Kandesn," a line of high quality skin, hair care and cosmetic products. Included within the "Sunergy" and other herbal supplement product lines are herbal dietary supplement tea beverages that ideally would include Stevia as an added dietary ingredient.

In 1982 Sunrider began marketing a product line that included "Nutrien Whole Food Concentrate," "Calli Tea," and "TruSweet Extract," all promoted for their health-related benefits. The *TruSweet Extract* was made from the Stevia herb and marketed in one ounce containers. At that time Sunrider was aware of the health-related benefits of Stevia associated with a body's regulation of blood sugar. This Stevia product was also marketed in 1984 under the trade name "Sunectar" as a dietary ingredient for use with "Calli Tea" and "Nutrien Whole Food Concentrate." Sunrider intended that the product would be used as a "special dietary food" to aid in weight management by having consumers place a drop of the liquid product on their tongues.

Sunectar, like *TruSweet*, was intended to be used for its special nutritional qualities which included helping the body establish a proper blood sugar level. Enclosed as Exhibit A are copies of 1984 product catalogues from Sunrider that discusses

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both *TruSweet* and *Sunectar* and their intended use for special dietary food purposes.

A review of Exhibit A indicates that Sunrider in 1984 was promoting and marketing Stevia as a nutritional food. (The Sunrider publication dated October 1984, at page 10, states: "*Sunectar*" [i.e. Stevia] "can be used alone to appease the appetite by placing a drop on the tongue. It has special nutritional qualities of its own. '*Sunectar*' helps the body help itself in establishing balance in blood sugar levels." (Emphasis added.) This promotional labeling used by Sunrider in October of 1984 clearly establishes the intended use of "*Sunectar*" for its nutritional benefits independent from the recognized sweetening characteristics of Stevia. The nutritional qualities of "*Sunectar*" are important for its use as a supplement to help the body regulate blood sugar.^{1/} This health-related use is similar to the intended use of other dietary ingredients for their health benefits (i.e. Chromium for impaired glucose tolerance and fiber to lower plasma cholesterol levels.^{2/}

As further evidence of the use and marketing of Stevia by Sunrider as a dietary ingredient in its *TruSweet* extract product, enclosed as Exhibit B is a copy of a 1984 Sunrider order form and invoice showing the availability for sale of *TruSweet Extract* and *Sunectar* and a facsimile copy of the bottle labeling for *Sunectar* showing as one of its ingredients "Yerba dulce" (i.e. Stevia) and a suggested use of 2 to 5 drops. *TruSweet* and *Sunectar* with Stevia included as a dietary ingredient were both sold throughout the United States for their special dietary food properties to assist in conditions of overweight and other health-related benefits.^{3/} The marketing of a special dietary food by legal

1/ See Curi R. Alvarez M. Bazotte RB, Botion LM, Godoy JL Bracht A, "Effect of Stevia Rebaudiana on Glucose Tolerance in Normal Adult Humans," *Brazilian Journal of Medical and Biological Research* (1986) 19(6); 771-4.

2/ See 10th Edition *Recommended Dietary Allowance* published by National Research Council, at pp. 4 and 242.

3/ See 21 CFR § 105.3(a)(1)(i) and Section 411(c)(3)(A) of the FDC Act.

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definition would include ingredients in those foods being considered as a dietary substance.^{4/}

Unfortunately, FDA objected to Sunrider's marketing of Stevia products as special dietary foods because the agency at that time considered Stevia to be an unsafe food additive. On July 30, 1984, FDA initiated a judicial seizure action against various Stevia products owned by Sunrider. Notwithstanding Sunrider's position that Stevia could be legally marketed as a generally recognized as safe ("GRAS") special dietary food, Sunrider decided it was not financially prudent to judicially contest this matter. As a result, Sunrider entered into a Consent Decree that prohibited it from selling *TruSweet Extract* or similar products containing Stevia, unless FDA approved its use as a food or it was not subject to the misbranding or adulteration sections of 21 U.S.C. § 381(d)(1). From the time of the Consent Decree to present, Sunrider has used Stevia only as a cosmetic ingredient in the United States.

The above Consent Decree creates additional uncertainty concerning Stevia and is a further reason why Sunrider requires written concurrence from FDA that Stevia can be imported and marketed as a dietary supplement ingredient.

**II. DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT OF 1994 (DSHEA)
(PUB.L. 103-417), 108 STAT. 4325, OCTOBER 25, 1994**

Because the legal status of Stevia is defined by DSHEA, a discussion of its applicable sections is necessary. The provisions of DSHEA are amendments to the Food, Drug, and Cosmetic Act (FDC Act), and add changes to the Act begun by the Nutrition Labeling and Education Act of 1990. The new legislation provides an extended definition of "dietary supplement" to be certain about the products and ingredients that are subject to the new DSHEA provisions.

^{4/} See Section 411(c)(3)(B) of the FDC Act which indicates in part special dietary use includes "Supplying a vitamin, mineral, or other ingredient for use by man to supplement the diet by increasing the total dietary intake." (Emphasis added.)

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A. Definition of "Dietary Supplement"

A "dietary supplement" is defined as a product . . . intended to supplement the diet that bears or contains one or more of "certain specified dietary ingredients." These include, "a vitamin", a "mineral," an "herb or other botanical," an "amino acid," a dietary substance for use by man to supplement the diet by increasing the total dietary intake" and "a concentrate, metabolite, constituent, extract, or combination" of any of the foregoing ingredients. (Emphasis added.) See Section 201 (ff)(1) of FDC Act, 21 U.S.C. § 321(ff)(1).

The new law arguably settles a fundamental definitional matter of providing a broad expansive definition of "dietary supplement" to include products that FDA traditionally has regarded as not having any nutritional value.

The new act further requires a dietary supplement to be in the form of a "tablet . . . powder . . . or liquid droplet, or be in some other form that is not represented as a 'conventional food.'" (Emphasis added.)^{5/}

The new law changes the FDC Act so that products that "simulate . . . conventional food (for example, a cracker or wafer that resembles a conventional food, or a tonic, tea, or protein shake that resembles a conventional beverage) will be eligible for dietary supplement status as long as they are not "represented" as conventional foods.^{6/}

B. Dietary Supplements Deemed to be Foods

The DSHEA in Section 3 provides that, "[e]xcept for purposes of section 201(g), a dietary supplement shall be deemed to be a food." This new provision will allow dietary supplement products

5/ See Section 201(ff)(2) of the FDC Act; 21 U.S.C. § 321(ff)(2).

6/ See Section 201(ff)(2) of the FDC Act, 21 U.S.C. § 321(ff)(2).

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to be legally regulated as foods by FDA even if they are not used primarily for their taste, aroma or nutritional value.^{7/}

C. Exemption From "Food Additive" Status

One of the key aspects of the new law that impacts the status of Stevia is the provision that the term "food additive" no longer applies to a dietary ingredient in, or intended for use in, a dietary supplement.^{8/}

Under the FDC Act, the agency in the past would argue that any substance added to a food that is not considered "GRAS" is subject to regulation as a "food additive" which may not be used until and unless FDA issues a regulation explicitly permitting such use. In the past, as with Sunrider's TruSweet product, FDA has frequently alleged "unapproved food additive" status against many popular dietary supplement ingredients. The new DSHEA eliminates this risk for dietary ingredients used in dietary supplements.

D. New Safety Standards

As a trade off for eliminating food additive status, the new law replaces the food additive provisions with some new safety standards for dietary supplements.

The DSHEA provides, in Section 4, that a dietary supplement may be "adulterated" if it "presents a significant or unreasonable risk of illness or injury under . . . conditions of use recommended or suggested in the labeling. . . ." The DSHEA specifically provides that FDA "shall bear the burden of proof" in court if it asserts that a dietary supplement is adulterated under this standard.^{9/}

There are additional requirements for a new dietary ingredient, i.e. - an ingredient that was not marketed in the

7/ See Section 201(ff)(3) of the FDC Act; 21 U.S.C. § 321(ff)(3).

8/ See Section 201(s)(6) of the FDC Act; 21 U.S.C. § 321(s)(6).

9/ See Section 402(f)(1) of the FDC Act; 21 U.S.C. § 342(f)(1).

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United States before October 15, 1994. A dietary supplement that contains a new dietary ingredient is deemed to be adulterated under Section 402(f) unless, either (1) the supplement "contains only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered," or (2) there is a "history of use or other evidence of safety establishing that the dietary ingredient . . . will reasonably be expected to be safe." In the latter case, also, "at least 75 days before" introducing the product or ingredient the manufacturer or distributor provides FDA "with information . . . which is the basis on which the distributor or manufacturer has concluded that a dietary supplement containing such ingredient will reasonably be expected to be safe."^{10/}

Sunrider believes there is a firm legal basis to market Stevia as an herb or botanical dietary ingredient specifically provided for in Section 201(ff) that is not considered to be a "new dietary ingredient" under Section 413(c) of the Act because it was marketed in 1982 as a special dietary food as well as an ingredient with dietary and nutritional benefits.

E. Stevia is Legally a
"Grandfathered" Or "Old" Dietary Ingredient

As evidence of the industry marketing of Stevia, enclosed as Exhibit C are copies of formulation extract worksheets from East Earth Herb, Inc. located in Eugene, Oregon showing the use of Stevia as an additional dietary ingredient in a ginseng herbal product that finished production on March 20, 1990 and was subsequently sold. (Additional information on the labeling of this product is available if needed.) Enclosed as Exhibit D are facsimile copies of the labeling for three herb tea products marketed by the Traditionals Company, now located in Sebastopol, California. A review of this exhibit shows the products were marketed as special dietary foods which included Stevia Leaf as an added dietary ingredient. The directions on the label call for the use of adding a sweetener if desired. The labeling clearly establishes that Stevia was included in the product as a dietary ingredient and not for any intended sweetening use. There is also a 1985 copyright notice on the labeling.

^{10/} See Sections 413(a) and (c) of the FDC Act.

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Sunrider considers its use of Stevia from 1982 to 1984 as a dietary ingredient, and the above-discussed industry use as an ingredient in other marketed special dietary food and ginseng products in 1985 and 1990 to be substantial evidence that it was extensively marketed as a dietary (i.e. herb or botanical) ingredient in the United States before October 15, 1994. There is, of course, no requirement in Section 413(c) that an "old" dietary ingredient be marketed for any specific dietary or other or other use. Any use of the ingredient deemed by DSHEA to be a dietary ingredient before October 15, 1994, should be legally sufficient. Stevia, therefore, should have the status of an "old" or "grandfathered" dietary ingredient that is deemed legally to be a food and cannot be regulated by FDA as an unsafe food additive.

In summary, Sunrider considers that the provisions of DSHEA established in Section 201(ff) of the Act a definition for the term "dietary supplement" that includes a product that contains dietary ingredients one of which is "an herb or other botanical" (i.e. Stevia), and which dietary supplement ingredient was marketed as early as 1982. Having met the two legal requirements provided in Section 413(c) of the Act, Stevia can not be considered by FDA as a "new dietary ingredient." For that reason, Sunrider considers the Stevia import alert should not be applicable to its intended importation of Stevia for use as a "grandfathered" dietary ingredient. Based on the above discussions and exhibits, Sunrider believes that FDA has no basis for not providing written confirmation to Sunrider that Stevia may be imported as a safe and suitable dietary supplement ingredient.

III. 75-DAY NOTIFICATION TO FDA OF INTENT TO MARKET STEVIA

Although Sunrider considers there is a firm legal basis to consider Stevia to be a "grandfathered" dietary ingredient, it is aware that FDA has provided very little guidance concerning DSHEA or the agency's position on "grandfathered ingredients." Because Sunrider is interested in marketing Stevia as soon as possible, it does not want to enter into protracted discussions with FDA over its status as an "old" dietary ingredient. For that reason,

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Sunrider feels it is prudent to provide FDA with an additional legal basis to began marketing Stevia in the United States.^{11/}

Therefore, as a separate and additional legal basis for the marketing of Stevia, Sunrider alternatively requests FDA accept this letter as the required 75-day notification to the agency of its intent to introduce Stevia for sale as a new dietary ingredient in the United States.^{12/} As previously discussed, the new legislation provides that a "new dietary ingredient" must have a history of use or other evidence of its safety. In addition, 75 days prior to marketing a manufacturer or distributor of a new dietary ingredient must provide to FDA "information" including any citations to published articles, which provides a reasonable basis for the manufacturer or distributor to conclude that a new dietary ingredient or dietary supplement is safe.

In respect to the legal requirements for marketing the new dietary ingredients, Sunrider is aware that it is a prohibited act to place in interstate commerce a dietary supplement that is unsafe within the meaning of Section 413 of the Act.^{13/} Presumably to be legally considered an unsafe dietary supplement

^{11/} Sunrider is also aware that if a Stevia product was marketed as a single entity dietary ingredient for dietary supplement use, FDA could not legally regulate it as an unsafe food additive. See U.S. v. Black Currant Oil 984 F.2d 814 (7th Cir. 1993) where the Court of Appeals affirmed a district court decision in which the court stated: It is important to note that the statutory definition of a substance under the [FDC] Act does not depend on any inherent properties of the substance, but rather depends on how the vendor of the substance intends the substance to be used." The court cited National Nutritional Foods Ass'n v. Mathews, 557 F.2d 325, 333 (2d Cir. 1977) for this position. Sunrider considers this legal theory unnecessary based on the regulation of herbs and botanical ingredients as foods under the provisions of DSHEA.

^{12/} See Section 413(a)(2) of the FDC Act.

^{13/} See Section 301(u) of the FDC Act.

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under Section 413, a product must be considered adulterated under Section 402(f)(1) of the Act. For a food to be adulterated under Section 402(f)(1), it must contain a dietary ingredient that is considered to be a "new dietary ingredient for which there is inadequate information to provide a reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury."^{14/} This legally required standard of safety is what Sunrider believes the FDC Act requires for Stevia to be considered safe as a new dietary ingredient. Based on that legal standard in determining the safety of Stevia, the following "information" is provided:

(1) Copy of Petition from American Herbal Products Association (AHPA) to FDA commissioner, Dr. David A. Kessler, M.D., J.D., dated October 21, 1991, to establish Stevia as GRAS for as a sweetening agent. (Exhibit E)

Sunrider is aware that FDA has previously received, but not accepted for filing, the enclosed GRAS Stevia petition by AHPA. It is being included only for purposes of demonstrating the extensive safety information available for Stevia and to show its long history of safe food use.

(2) Article from Trends on Analytical Chemistry Vol. I, No. 11, 1982, entitled "Steviol-glycosides: New natural sweeteners." Please note the conclusion of the author that "No possible mutagenic activity has been observed for Stevioside, Rebaudioside A or crude extracts of Stevia Rebaudiana using the AMES test." (Exhibit F)

(3) Article from the Food Industry, Vol. 22, No. 22 (1979) entitled "Safety and Utilization of Stevia Sweetener." Please note on page 6 of the article the discussion on the use of Stevia for "low calorie foods" where the author states "It is useful for prevention of obsity [sic] [obesity], dental cavities, diabetes therapy and is an effective sweetener for low calorie foods." This article further confirms the long history of use of Stevia as a special dietary food. (Exhibit G)

(4) Article (dated March 16, 1992) entitled "Food Ingredient Safety Review - Stevia Rebaudiana Leaves" prepared for

^{14/} See Section 402(f)(1)(B) of the FDC Act.

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the Herb Research Foundation by A. Douglas Kinghorn, Ph.D., Professor of Pharmacognosy, College of Pharmacy, University of Illinois at Chicago. Please note on page three of the author's Summary and Conclusions the statement "Since no negative clinical reports have appeared as the result of the consumption of Stevia Rebaudiana Leaves in any of the countries where they are available, it may be concluded that, on the basis of these observations, these materials (i.e. Stevia) present virtually no toxicity risk to humans." The report also includes the extensive acute and chronic animal testing that has been undertaken to demonstrate the safety of Stevia for food or dietary supplement use. (Exhibit H)

(5) Document entitled "Stevia Abstracts" which is a compilation of clinical study and patent abstracts on Stevia prepared by Sunrider showing over 500 different "citations to published articles"^{15/} that involves the safe use of Stevia. (Exhibit I)

(6) Sunrider's international product registrations for "Sunectar" (Stevia) for the countries of Thailand, Indonesia, Mexico and Japan, which allow the importation and sale of Sunectar as a safe food product. (Exhibit J)

Sunrider considers the enclosed "information" to be substantial evidence of the worldwide long and safe use of Stevia for food and dietary supplement products. The enclosed documentation including the previously submitted AHPA Stevia GRAS petition is more than what is legally required to meet the statutory requirements of Section 402(f)(1)(B) of the Act to show that Stevia when used as a dietary ingredient at a labeled recommended use of one to five drops or in mg quantities could not present a significant or unreasonable risk of illness or injury.

IV. CONCLUSION

Sunrider considers that the documentation provided to FDA with this letter establishes Stevia as an ingredient subject to Section 201(ff)(1)(C) and 413(c) of the FDC Act to be a safe and

^{15/} See Section 413(a)(2) of the FDC Act.

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suitable herb or botanical dietary ingredient that was marketed in the United States before October 15, 1994. Stevia was marketed for use in herbal dietary food and beverage products and individually as a special dietary food for weight management. This use was established by the 1984 Sunrider catalogue and its additional marketing in other herbal tea and ginseng products. Sunrider considers these documented uses of Stevia to establish it legally as an "old" dietary ingredient that cannot be regulated by FDA as an unsafe food additive. On this basis, Stevia should be allowed for immediate sale and marketing in the U.S. Because it has been subject to regulatory action from FDA for its past use of Stevia and the fact FDA is still enforcing the Stevia Import Alert, Sunrider considers it extremely important to receive written assurance from FDA that the agency concurs with its legal position that Stevia is a "grandfathered" dietary ingredient and can be legally used in dietary supplement products.

Alternatively, and as a separate legal basis for the marketing and use of Stevia as an ingredient for dietary supplement products, Sunrider is submitting this letter as the 75-day notification to FDA required by Section 413(a)(2) of the Act.^{16/} The enclosed "information" provides the legal basis for establishing that Stevia is not an adulterated food because it is a dietary ingredient based on its recommended use that does not

^{16/} Sunrider is further aware that under Section 413(a)(2) of the Act that FDA is required to keep confidential the information provided by Sunrider for 90 days of receipt at which time it is placed on public display. Sunrider believes that upon reviewing this submission if FDA determines that Stevia can be sold as a "grandfathered" dietary ingredient, the enclosed 75-day notice of marketing and enclosed "information" (i.e. Exhibits E - J) is not legally required. For that reason, Sunrider assumes that FDA would keep this submission and enclosures as confidential material and promptly return them to Sunrider. If FDA does not intend to keep this submission and enclosures as confidential based on the above discussion, Sunrider needs to be appropriately notified.

W. PATRICK NOONAN, P.C.

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present a significant or unreasonable risk of illness or injury.^{17/}

Sunrider is equally confident the enclosed information as well as the previous GRAS petition by AHPA adequately proves that Stevia has a long history of worldwide use as a safe food and is sufficient to meet the legal standards of Section 402(f)(1)(B) of the Act to market a new dietary ingredient.

However, in deference to FDA's authority and interest in this matter, Sunrider does not wish to place at risk the considerable economic resources needed to import and market Stevia with the possibility of a conflict with FDA over the correct legal status of Stevia. For that reason, Sunrider considers it certainly equitable and fair to insist that within 75 days of this letter FDA provide a written response outlining the agency's concurrence or objections to the alternative legal positions of Sunrider presented in this letter for the marketing of Stevia. If FDA fails to respond within this 75-day period (i.e. by July 1, 1995), Sunrider will assume that the agency agrees with its legal position and will not object to the marketing of Stevia in the United States as a suitable and safe dietary ingredient. If FDA fails to provide a timely response and later asserts that the agency disagreed with the legal position of Sunrider by subjecting Stevia to an import detention or other enforcement action, Sunrider will have no alternative but to seek judicial relief. This is not a result FDA should encourage or want.

Sunrider is submitting this letter in a good faith effort to fully explain its legal position for marketing Stevia before importing the material and, therefore, feels that FDA must also act in good faith by providing an expedient and timely response.

If it would be helpful in resolving the important issues prescribed, we would be pleased to meet with your office or with other FDA personnel, and representatives of Sunrider are also ready to come to Washington, D.C. from California to discuss more fully with agency representatives any or all other issues.

^{17/} See Section 402(f)(1)(B) of the FDC Act.

W. PATRICK NOONAN, P.C.

Dr. Elizabeth A. Yetley
Re: Stevia Rebaudiana Bertoni
April 17, 1995
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If FDA should require further information on Stevia or have any other questions concerning this letter, please contact me as soon as possible.

Sincerely,



W. Patrick Noonan

WPN/DLL
Enclosures
cc: Holly Vanderdonck (w/Enclosures)