DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

AUG 28 2001

Mr. R. Elliott Dunn, Jr.
General Counsel
Strictly Supplements, Inc.
2920 N. Green Valley Parkway
Building 3, Suite 321
Henderson, Nevada 89014

Dear Mr. Dunn:

This is in response to your letter of December 22, 2000 to the Food and Drug Administration (FDA). Your letter responds to our letter to you dated October 13, 2000 concerning your July 7, 2001 submission pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)) for the product Citr-A-Sol.

In your letter, and the letter from Ralph Fucetola, III on your behalf that you included with your letter, you state that you disagree with our determination that your product can not be lawfully marketed as a dietary supplement because it violates the FD&C Act. The agency has considered the information in your most recent letter and nothing in your letter, nor in the letter from Mr. Fucetola, persuades us that our conclusion that this product is not a dietary supplement is wrong. The continued marketing of this product as a dietary supplement violates the FD&C Act and may subject you or the product to action under the FD&C Act without further notice.

Please contact us if you have any questions regarding this matter.

Sincerely,

for John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

975-0163

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Copies:
FDA, Office of Compliance, Center for Drug Evaluation and Research, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, San Francisco District Office, Office of Compliance, HFR-PA140
FDA, Florida District Office, Office of Compliance, HFR-SE 240

Strictly Supplements, Inc.
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TEL: (702) 547-9009 **FAX: (702) 898-7103**

73971

December 22, 2000

RECEIVED

RECEIVED 1/8/01

By Certified Mail

Mr. John B. Foret, Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety and Applied Nutrition
200 C Street SW
Washington, D.C. 20204

RE: Notice of Use of § 403(r)(6) Statements on Dietary Supplement Label and Labeling - Citr-A-Sol

Dear Mr. Foret:

Thank you for your October 13, 2000 response to my September 21, 2000 letter, requesting clarification of statements contained in your September 11, 2000 letter. SSI has reviewed and considered the conclusions set forth in your September 11 letter, as clarified by your October 13 letter.

First of all, based upon your statement that your "opinions and conclusions in this letter and the letter of September 11, 2000 are consistent with agency policy and practices" and were provided by you in your "official capacity as Director, Division of Compliance and Enforcement, Office of Nutritional Products, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition", SSI understands that your opinions and conclusions reflect the official position of the FDA with respect to the matters you address. If this is not correct, I would appreciate your advising me.

Secondly, SSI is aware of the decision of the United States Court of Appeals in **Pharmanex v. Shalala, 221 F.3d 1151 (10th Cir. 2000)**, which you point out. While this decision does lend support to your stated conclusion that any of the product's individual components may be an "article that is approved as a new drug" within the meaning of 21 U.S.C. 321(ff)(3)(B), this position is contrary to the FDA's prior interpretation that approval of a new drug is an approval of an entire

product only, and not an active ingredient of the product. This position is also contrary to decisions of the United States Supreme Court, which have held that new drug approval covered an entire product. Additionally, the Tenth Circuit remanded the **Pharmanex** case to the United States District Court for the consideration of the issues which were raised, but not decided, before the appeal was taken. Therefore, SSI does not believe that this decision merits the reliance the FDA seems to place upon it.

Third you acknowledge that the claims which SSI makes about Citr-A-Sol ("Helps maintain normal function of brain cells and promote a feeling of well-being" and ". . . to help maintain the normal function of brain cells, which tends to promote the feeling of well-being and enhances the quality of life . . ." are structure/function claims. This fact is the sole reason for SSI's notification letter dated July 7, 2000. SSI would not have been required to notify the FDA had it chosen not to make such claims about Citr-A-Sol.

You identify a letter on SSI letterhead as the information that the FDA considers as indicative that Citr-A-Sol is promoted and marketed in a manner that evidences that it is intended for use as a drug. You say your conclusion is based upon a belief that Citr-A-Sol was developed based upon a liquid deprenyl product developed by Discovery Experimental and Development, Inc. that Citr-A-Sol is the same product as liquid deprenyl; that it is marketed to the same customers as liquid deprenyl; and that liquid deprenyl was found to be a prescription drug by a jury in the criminal case of United States v. Kimball. This conclusion assumes that all of the beliefs on which it is based are matters of fact. This is an erroneous assumption. Citr-A-Sol was developed using knowledge gained by Discovery Experimental and Development, Inc. when it developed a liquid deprenyl product. Citr-A-Sol is not the same product as Discovery's liquid deprenyl and it was not promoted as the same product, but was offered as a different product, and without any claim or suggestion that it was intended for use as a drug. Nor was the offer to sell Citr-A-Sol limited to customers who might have previously purchased liquid deprenyl, but rather, it was offered to a much broader group of potential purchasers who had previously purchased other dietary supplements developed and marketed by Discovery. Finally, as you must know, the jury verdict in the case of United States v. Kimball was based upon the evidence introduced in the trial of that case, and is limited to that evidence. Such verdict is irrelevant to any consideration of Citr-A-Sol's intended use. SSI promoted and marketed Citr-A-Sol solely as a dietary supplement, and has not suggested in any way that it is intended for any purpose other than as a dietary supplement. Any suggestion that Citr-A-Sol may be used to treat a disease would be made without any authorization or encouragement from SSI. As a matter of fact, SSI has expressly disclaimed the use of Citr-A-Sol as treatment for any disease, or for any other use that would suggest that it is intended for use as a drug.

Fourth, SSI gathered substantial scientific evidence, as well as obtained expert opinions, in advance of its decision to market Citr-A-Sol as a dietary supplement. All of that evidence, and the opinions from scientific experts, support SSI's position that all of the ingredients in Citr-A-Sol are ingredients which meet the definition of dietary supplements contained in 21 U.S.C. § 321(ff)(1). Based upon that evidence and those opinions, SSI believes that the ingredient selegiline qualifies

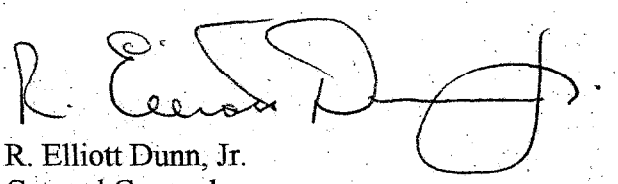
under such definition as an extract of a "botanical", and that the other ingredients similarly satisfy one, or more, of the defined ingredients of dietary supplements. If this is true, then it is not necessary, that in addition, either selegiline, or any of the other ingredients, must also satisfy the definition of "dietary substance" under 21 U.S.C. § 321(ff)(1)(E). Further, SSI is not aware of any generally recognized scientific evidence that selegiline itself may result in serious adverse reactions when used in combination with certain drugs, foods or drinks. To the contrary, SSI is aware of generally recognized scientific evidence that selegiline itself has not resulted in any serious adverse reactions when used in combination with certain drugs, foods or drinks, but rather, is safe for use as a dietary supplement according to the directions for such use.

Additionally, your assertions that Citr-A-Sol is a drug, a new drug, an unapproved new drug, and therefore illegal for introduction into interstate commerce, and that a dietary supplement containing selegiline is therefore adulterated, are considered to be unwarranted on any factual or legal basis that SSI is aware of. Citr-A-Sol has never been determined by the FDA to be a drug, nor has SSI even sought FDA approval for Citr-A-Sol as a new drug. As mentioned above, SSI makes no claims that Citr-A-Sol is intended for any use other than as a dietary supplement. And, as to the assertion that a dietary supplement containing selegiline is thereby adulterated, such assertion is simply groundless. If that is a position the FDA wishes to pursue, then it appears that under 21 U.S.C. § 342, the burden is upon the United States to establish such adulteration.

Finally, SSI does have concerns for consumer safety and would not knowingly distribute any product that jeopardized the safety of the consumer of any of its products. This concern, however, was not the reason that SSI suspended distribution of Citr-A-Sol. Rather, the reason SSI suspended distribution was the threat of the FDA contained in your September 11, 2000 letter, to take action against SSI and Citr-A-Sol without any warning or notice, which you have now represented to be an official position of your agency.

In summary, SSI strongly disagrees with the conclusions that you reach in your letter. As pointed out at the beginning of this response, SSI believes that the basic assumptions from which you begin are fatally flawed. SSI believes that Citr-A-Sol is a bona fide dietary supplement, and that it can marketed as such. SSI has not utilized any promotional or marketing information to suggest that Citr-A-Sol is intended for use as anything but a dietary supplement, nor does it intend to do so.

Sincerely,



R. Elliott Dunn, Jr.
General Counsel

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October 3, 2000

John B. Foret
Director
Division of Compliance and Enforcement
Food and Drug Administration
Washington, DC 20204

Dear Mr. Foret

I have reviewed your letter dated September 11, 2000 sent to Strictly Supplements, Inc. (S.S.I.) with regard to Citr-A-Sol™.

Firstly, the letter appears to be a letter from an employee of the FDA under 21CFR10.85 rather than an official letter under 21USC3371 5USC3553, 21CFR3101.90 and as set forth under the Dietary Supplement Health and Education Act of 1994 (DSHEA).

Under DSHEA, the FDA must follow the procedures set forth, Notification, Hearing if requested, and follow through with the administrative process of proving their position under DSHEA. The FDA has the burden of proving their position as to whether or not Citr-A-Sol is a Dietary Supplement or not or is labeled properly.

In my previous correspondence with S.S.I., I rendered an opinion that Citr-A-Sol as presented and as labeled was a Dietary Supplement. The fact that there is expert testimony from noted Scientists and Doctors that all the ingredients within Citr-A-Sol qualify under DSHEA as Dietary Supplements reaffirms my position that Citr-A-Sol is indeed a supplement as labeled, not a drug, as suggested by the FDA.

You suggest that Selegeline is an active ingredient within an approved drug, therefore having Selegeline within Citr-A-Sol makes Citr-A-Sol somehow a drug by association. This was not the intent of Congress in adopting DSHEA. Congress, responding to public demand, intended the widest availability of dietary substances and truthful information about them.

I have been clearly advised that the active ingredient within FDA approved drugs is not what you suggest, Selegeline, but in fact the chemical entity *Selegeline Hydrochloride* is what is present in FDA approved drugs. I have also been advised that expert testimony admitted in Federal Court in the case *US vs Kimball et al.*, revealed that the chemical entity *Selegeline Hydrochloride* is not the same chemical entity as Selegeline or Selegeline Citrate. This in itself is enough reason to state that the FDA approved Selegeline or Deprenyl type product is definitely not the same as the Citr-A-Sol supplement which is intended for human ingestion as a dietary substance.

In *US vs Generex* the Supreme Court stated that a product or drug product consists of the entire product not any one ingredient or designated active ingredient. Also reflected in Generex is that a drug product using the same named chemical as an active ingredient made by different manufacturers is in fact not the same drug. The FDA obviously agrees with the Supreme Court regarding Generics, as the FDA demands an individual New Drug Application for each Generic or alleged duplicate drug product and requires extensive bio-equivalency testing to prove each Generic Drug Application is an equivalent drug product to the approved drug. Many Generic Drug Applications to the FDA are refused because of testing results revealing the products are not the same under extensive testing.

The Generex case clearly says to me, and I am sure anyone else, that the active ingredient or chemical within any product whether it be a drug or not is in fact not a drug by itself nor controlled by the FDA, even if the active ingredient were the same which is not the fact in the case of Strictly Supplements Inc. and Citr-A-Sol.

I have been advised that the chemical entity and dietary substance Selegeline only normalizes a tissue within the brain called the *substantia negra*, which in turn protects brain cell degeneration. In that regard Citr-A-Sol would definitely qualify as a nutrient as its action promotes a healthy body, as does Vitamin C, Calcium, and the varied list of nutrients classified under DSHEA as dietary substances.

I have not changed my opinion regarding Citr-A-Sol being a Dietary Supplement under DSHEA just because Mr. Foret, not acting under the required regulation, has a different stance. The product with its ingredients is a Dietary Supplement and labeled properly under DSHEA.

However, in the utmost precaution because the FDA has taken the position they have, which I believe is totally improper and not within the guidelines of DSHEA at all, I have suggested to S.S.I. changing the claims on the label to say: "This nutrient supports normal structure and function and may improve your quality of life." and nothing regarding medical claims. I think it would be exceedingly difficult for you to misconstrue that statement as a *medical* claim. It is my advice and opinion that the suggested statement is not a medical claim in any fashion. Also, in the utmost precaution I recommended the removal of the old D.E.D.I. logo as the FDA could misconstrue that logo as creating a relationship to an product which did state truthful medical claims.

If Citr-A-Sol were promoted by S.S.I. as a dietary supplement product that only claimed that it may improve quality of life, I cannot foresee any complaint the FDA could have regarding my legal stance, advice and opinion. S.S.I. may rely upon this opinion and the statutory basis for the "normal structure and function" claim which S.S.I. is entitled to make under DSHEA.

However, if the FDA wants to hassle S.S.I. you have the power to do so and there is little S.S.I. can do except go through the Court System. As we have learned, over and over again (see, for example, *Pearson v FDA*) the government agency often loses in Court and the intent of Congress under DSHEA is upheld.

To avoid the continued FDA harassment of S.S.I. the company always has the alternative to set up a manufacturing facility in every state, produce and sell Citr-A-Sol within each state and totally avoid any FDA "interstate commerce" jurisdiction over the company or its products. Of course, Congress did not intend Americans to have to go to such lengths to exercise the rights that are secured by DSHEA. To exercise those rights one need only have a product which qualifies as a dietary substance (which Citr-A-Sol does) and a complying label, stating "dietary supplement" -- making only allowed Structure and Function claims under the FDA promulgated Rule. This, in my opinion, S.S.I. will have done. I hope the FDA will reconsider the position taken in the letter of September 11, 2000 to avoid unnecessary litigation which will not further any legitimate regulatory purpose, but will only serve to, at best, temporarily delay the consumer's access to a simple dietary substance that supports normal structure and function.

Very truly yours,

Ralph Fucetola III

cc: Mr. R. Elliott Dunn, Jr.
General Counsel
Strictly Supplements, Inc.