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

Dear Mr. Dunn:

This is in response to your letter to the Food and Drug Administration (FDA) dated September 21, 2000. Your letter responds to our letter dated September 11, 2000 concerning your July 7, 2000 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, you asked FDA to clarify certain statements made in our September 11, 2000 letter. Our responses to your questions are set forth below.

What is the basis for our statement that “either an entire product, or any of a product’s individual components may be an ‘article that is approved as a new drug’ or an article ‘authorized for investigation as a new drug’ within the meaning of 21 U.S.C. 321(ff)(3)(B).”

The United States Court of Appeals for the Tenth Circuit upheld this interpretation of 21 U.S.C. 321(ff)(3)(B) on July 21, 2000 in Pharmanex v. Shalala, 221 F.3d 1151 (10th Cir. 2000) (enclosure 1).

When and how was selegiline approved as a new drug? Upon what do you base the statement that selegiline was not marketed as a dietary supplement or as a food additive?

FDA approved a new drug application for selegiline submitted by Somerset Pharmaceuticals on January 5, 1989 under 21 U.S.C. 355 and 21 CFR part 314. Subsequent abbreviated new drug applications for selegiline have been approved by FDA and can be found in the “Orange Book” on FDA’s website (<http://www.fda.gov/cder/ob/default.htm>).

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Selegiline is not an approved food additive in any FDA regulation (see 21 CFR Part 172). Moreover, FDA is not aware of any body of scientific evidence that would establish that selegiline is generally recognized as safe (GRAS) for use in food, thus enabling it to be lawfully marketed as a food or dietary supplement.

What information is FDA aware of that Citr-A-Sol is promoted and marketed in a manner that evidences that it is intended for use as a drug?

A letter on Strictly Supplements, Inc. letterhead indicates that the product was developed based on a liquid deprenyl product developed by Discovery Experimental and Development, Inc. Citr-A-Sol is promoted as the same product and is marketed to the same customers as liquid deprenyl, a product that the jury in *United States v. Kimball* determined to be a prescription drug.

What is the basis for FDA's statement that selegiline is not a dietary ingredient under the definition of supplement in the FD&C Act and that it is not a dietary substance for use by man to supplement the diet by increasing the total dietary intake?

The basis for our conclusion that selegiline is not a dietary ingredient under 21 U.S.C. 321(ff)(1) was stated in our September 11, 2000 letter. It is repeated here. Selegiline is not a dietary ingredient under the definition of a dietary supplement in the FD&C Act. Under 21 U.S.C. 321(ff)(1), a dietary supplement is defined, in part, as a product that contains one or more dietary ingredients that are a "vitamin," a "mineral," an "amino acid," and "herb or other botanical," a "dietary substance for use by man to supplement the diet by increasing the total dietary intake," or a "concentrate, metabolite, constituent, extract, or combination" of any ingredient named above. Selegiline is not a vitamin, mineral, herb or other botanical, or an amino acid (21 U.S.C. 321(ff)(1)(A-D)).

It is also not a "dietary substance for use by man to supplement the diet by increasing the total dietary intake" (21 U.S.C. 321(ff)(1)(E)). The term "dietary substance" is not defined in the FD&C Act or the statute's legislative history. The term must, therefore, be interpreted in accordance with its common, usual meaning. According to Webster's II New Riverside University Dictionary, "dietary" means "of or relating to diet," diet means "an organism's usual food and drink," and "substance" generically refers to "that which has mass, occupies space, and can be perceived." "Dietary substance," therefore, means anything commonly perceived as part of man's usual food or drink. Selegiline is the active ingredient in an approved NDA, specifically, Eldepryl. It is not a part of man's usual food or drink. Indeed, this substance has been known to be associated with

Page 3 - Mr. R. Elliott Dunn, Jr.

significant adverse reactions when used with other drugs or with certain foods and beverages. Nor is it a dietary ingredient described in 21 U.S.C. 321(ff)(1)(F), that is, a concentrate, metabolite, constituent, extract, or combination of any ingredient described above.

Are the opinions and conclusions expressed in FDA's September 11, 2000 letter the personal opinion of the signatory of that letter or are they the official position of FDA?

The opinions and conclusions in this letter and the letter of September 11, 2000 are consistent with agency policy and practices and were provided by me in my official capacity as Director, Division of Compliance and Enforcement, Office of Nutritional Products, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition.

Finally, I would like to express my appreciation for the concern for consumer safety shown by your willingness to suspend distribution of Citr-A-Sol. Please contact us if you have any questions regarding this matter.

Sincerely,



John B. Foret

Director

Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Enclosure

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-SE240

Page 4 - Mr. R. Elliott Dunn, Jr.

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFD-40 (Behrman)

HFD-310

HFD-314

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-810

HFS-811 (file)

HFS-607 (Delgado)

HFV-228 (Benz)

GCF-1 (Dorsey, Nickerson, Fox, Jones)

r/d:HFS-811:RMoore:9/28/00

revised per GCF-1:DDorsey/JJones:9:29:00

revised per HFS-810:Foret:10/10/00

Init:GCF-1 (Dorsey):10/11/00

f/t:HFS-811:rjm:10/10/00:docname:72626.adv:disc51

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September 21, 2000

By Facsimile and Certified Mail

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Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety and Applied Nutrition
200 C Street SW
Washington, D.C. 20204

SEP 23 2000

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

Dear Mr. Foret,

This is in response to your letter of September 11, 2000, with respect to my notice of July 7, 2000, on the above referenced dietary supplement distributed by Strictly Supplements, Inc. ("SSI"). I have discussed your letter with my client, and can tell you that SSI disagrees with most of the statements and conclusions set forth therein. However, because of your threat of undefined action against SSI or the product without further notice, I have suggested to SSI that it consider suspending its distribution of Citr-A-Sol for the time being, and it has voluntarily done so, effective upon my receipt of your letter. SSI does not wish to be subjected to unwarranted action, or have its product subjected to such action, simply because it sought to comply with notification requirements regarding claims to be made in connection with distribution of a dietary supplement.

I have also suggested to SSI, that before it makes any determination as to its position on the conclusions you set forth in your letter, and responds thereto, we request additional information and clarification as to those conclusions, so that it might evaluate such information in reaching its own conclusions. In your letter, you invited us to contact you if we have any questions regarding this matter, and we are accepting that invitation. I hope you were serious when you extended this invitation, because the information you furnish to SSI in response to its questions will undoubtedly be helpful to SSI in making an informed decision about its product, Citr-A-Sol.

Mr. John B. Foret
September 21, 2000
Page 2

The following are the statements in your letter about which SSI has questions:

(a) **Your statement:** Either an entire product, or any of a product's individual components may be "an article that is approved as a new drug" or an article "authorized for investigation as a new drug" within the meaning of 21 U.S.C. § 321(ff)(3)(B). **Question:** Since this section you refer to does not specify either an entire product or any of a product's individual components, what is the basis for that statement?

(b) **Your Statement:** Selegiline was not marketed as a dietary supplement or as a food before its approval as a new drug. **Questions:** When and how was selegiline approved as a new drug? Upon what do you base the statement that selegiline was not marketed as a dietary supplement or as a food additive?

(c) **Your Statement:** The FDA is aware of other information that Citr-A-Sol is promoted and marketed in a manner that evidences that it is intended for use as a drug, in that it is promoted as a treatment for disease. **Question:** What is this other information the FDA is aware of, and what is its source?

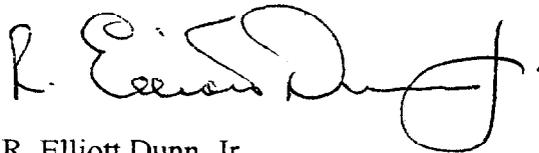
(d) **Your Statement:** Selegiline is not a dietary ingredient under the definition of dietary supplement in the FD&C Act. **Question:** Upon what do you base this statement?

(e) **Your Statement:** Selegiline is also not a dietary substance for use by man to supplement the diet by increasing the total dietary intake. **Question:** Upon what do you base this statement?

(f) **Your Statement:** Citr-A-Sol is a drug, a new drug, and an unapproved new drug, and it is illegal to introduce it or deliver it for introduction into interstate commerce. **Questions:** As to this statement, and the other statements references in (a) through (e) herein, are these your individual opinion and conclusions, or do such opinions and conclusions represent the official position of the FDA? If these opinions and conclusions are represented to be the official position of the FDA, what procedure was followed in arriving at such position, and under what authority was this done?

You can be confident that SSI will consider any information you furnish in response to the above questions in evaluating its position with respect to Citr-A-Sol; however, because of the voluntary suspension in marketing the product, I would appreciate receiving your response within 10 days.

Sincerely,



R. Elliott Dunn, Jr.
General Counsel