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Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4519
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July 31, 2001

WARNING LETTER NO. 2001-NOL-41

**FEDERAL EXPRESS
OVERNIGHT DELIVERY**

Mr. Glenn A. Pruitt, President
PharmaScience Laboratories, LLC
136 Weisenberger Road, Suite B
Madison, Mississippi 39110

Dear Mr. Pruitt:

The U.S. Food and Drug Administration (FDA) has reviewed product labeling collected during an inspection of your firm, located at 136 Weisenberger Road, Suite B, Madison, Mississippi, between January 25, 2001 and February 2, 2001. Our review found that you have serious violations of Section 403 of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and the food and dietary supplement labeling regulations through links at FDA's home page <http://www.fda.gov>.

The products, Canyon World Quest C-4, Canyon World Quest H.E.L.P.TM, Canyon World Quest X-Treme N.R.G., Cypress Pharmaceutical, Inc. Calcium 600 mg, Cypress Pharmaceutical, Inc. Oyster Calcium 500 mg with Vitamin D, Cypress Pharmaceutical, Inc. Calcium 600 mg with Vitamin D, Cypress Pharmaceutical, Inc. Oyster Calcium 250 mg with Vitamin D, [REDACTED]

[REDACTED] and [REDACTED] are misbranded because the labels do not include the mandatory statement of identity required for dietary supplements, namely that the term "dietary supplement" appear as part of the statement of identity, or use the statement "as a dietary supplement" in the instructions for use, which is not a suitable alternative to the statutory requirement that a dietary supplement be "labeled as a dietary supplement" [Title 21, *Code of Federal Regulations*, Part 101.3(g) (21 CFR) and Sections 403 (i)(1) and 403(s)(2)(B) of the Act].

The products, Canyon World Quest C-4 and Canyon World Quest X-Treme fxTM, are misbranded under Section 403(r)(1)(A) of the Act because each of the labels bears an unauthorized nutrient content claim, "with Z-Guggulsterone" or "with *Citrus aurantium*," respectively. "Contains" is a nutrient content claim defined in 21 CFR 101.54(c). FDA considers "with" a synonym for "contains" in the context used on these labels. The claim "contains" is authorized for nutrients that have a Reference Daily Intake (RDI) [21 CFR 101.9(c)(8)(iv)] or Daily Reference Value (DRV) [21

CFR 101.9(c)(9)], provided that the food that bears the claim contains 10-19 percent of the RDI or DRV per reference amount customarily consumed [21 CFR 101.54(c)]. This claim is not authorized for substances without an RDI or DRV. Since there is no RDI or DRV for Z-Guggulsterone or *Citrus aurantium*, the claims “with Z-Guggulsterone” and “with *Citrus aurantium*” are unauthorized nutrient content claims that misbrand these products.

The products, Canyon World Quest C-4, Canyon World Quest H.E.L.P.™, Canyon World Quest X-Treme fx™, and Canyon World Quest X-Treme N.R.G., are misbranded under Section 403(e) of the Act because the labels of these products do not bear the name and place of business of the manufacturer, packer, or distributor [21 CFR 101.5].

The products, Canyon World Quest C-4, Canyon World Quest H.E.L.P.™, Canyon World Quest X-Treme fx™, and Canyon World Quest X-Treme N.R.G., are misbranded because they deviate from the prescribed labeling regulation by not separating dietary information for dietary ingredients that have a RDI or a DRV [see 21 CFR 101.36(b)(2)] established by regulation in 21 CFR 101.9(c)(8)(iv) from declared dietary ingredients for which RDI's and DRV's have not been established [21 CFR 101.36(b)(3), Section 403(q)(5)(F) of the Act and 21 CFR 101.36(e)].

The products, Cypress Pharmaceutical, Inc. Vitamin E-200 IU, Cypress Pharmaceutical, Inc. Vitamin C 500 mg, Cypress Pharmaceutical, Inc. Calcium 600 mg, Cypress Pharmaceutical, Inc. Oyster Calcium 500 mg with Vitamin D, Cypress Pharmaceutical, Inc. Calcium 600 mg with Vitamin D, Cypress Pharmaceutical, Inc. Oyster Calcium 250 mg with Vitamin D, Cypress Pharmaceutical, Inc. Vitamin C 250 mg, Cypress Pharmaceutical, Inc. Vitamin E-400 IU, [REDACTED] and [REDACTED] are misbranded because the labels bear NDC numbers but the products are not registered with FDA as drugs and, therefore, the presence of this label statement is false and misleading [Section 403(a)(1) of the Act].

The products, [REDACTED] and [REDACTED] are misbranded because they bear “nutrition facts” labels when they should instead bear “Supplement Facts” labels [21 CFR 101.36 and Section 403(q)(5)(F) of the Act].

The products, [REDACTED] and Cypress Pharmaceutical, Inc. Vitamin C 250 mg Adult Chewable Tablets, are misbranded because the labels use the term “inactive ingredients” instead of the term “other ingredients” which is required by regulation [21 CFR 101.4(g)].

The product, Cypress Pharmaceutical, Inc. Vitamin C 250 mg Adult Chewable Tablets, is misbranded because it declares sodium in the nutrition label but it may not because it is present in an amount less than 2% and because the order in which the ingredients are listed is not that required by regulation [21 CFR 101.36(b) and Section 403(q)(5)(F) of the Act].

The Cypress Pharmaceutical, Inc. products, Calcium 600mg and Calcium 600mg with Vitamin D, are misbranded because the “other ingredients” are not listed immediately below the supplement

facts panel, but incorrectly after the directions for use [21 CFR 101.36(i)(2)(iii) and Section 403(q)(5)(F) of the Act].

This letter is not intended to be an all-inclusive list of deficiencies in your labeling. It is your responsibility to ensure adherence to each requirement of the Act and regulations. You should review all of the labels of your products to assure that they comply with the Act and regulations.

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or obtaining a court injunction against further marketing of your dietary products.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date that you receive this letter, what steps you are taking to correct the problems. We also ask that you explain how you intend to prevent these violations from happening again. If you need more time, then let us know why and when you expect to complete your corrections.

Your written response should be directed to the attention of Ms. Rebecca A. Asente, Compliance Officer, at the above address.

Sincerely,



Carl E. Draper
District Director
New Orleans District

Enclosure: Form FDA 483