



DEC - 3 2004

Mr. Steve Snyder
President
21st Century Nutritional Products, Inc.
2119 South Wilson Street
Tempe, Arizona 85282-2034

Dear Mr. Snyder:

This is in response to your submissions to the Food and Drug Administration (FDA), dated October 29, 2004. Your submissions appear to be intended to be the notifications required by 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)) and 21 CFR 101.93(a) for products marketed by Discount Drug Mart, Medina, Ohio as dietary supplements.

21 CFR 101.93(a)(3) requires that the notice submitted pursuant to 21 U.S.C. 343(r)(6) and this section be signed by a responsible individual who can certify the accuracy of the information presented and contained in the notice, and that the individual certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading. Your submissions do not meet this requirement in that the notices do not contain the signature of a responsible individual nor does it certify that the firm is in compliance with the requirements of the Act and the regulation. Therefore, your firm has not complied with the notification requirement in 21 U.S.C. 343(r)(6) and must submit notifications in accordance with the requirements in 21 CFR 101.93(a). The failure to submit a valid notice as required by the Act and the agency's regulation may subject the products that are the subject of the notification to regulation under the drug provisions of the Act.

Please contact us if we may be of further assistance.

Sincerely yours,

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Los Angeles District Office, Compliance Branch, HFR-PA240

Copy:

President

Discount Drug Mart

211 Commerce Drive

Medina, Ohio 44256