



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service

**WARNING LETTER**  
**2004-DT-03**

Food and Drug Administration  
Detroit District  
300 River Place  
Suite 5900  
Detroit, MI 48207  
Telephone: 313-393-8100  
FAX: 313-393-8139

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

January 16, 2004

Ayed Shweihat, R.P.H.  
White Lake Pharmacy  
9215 Highland Rd.  
White Lake, MI 48386

Re: Ayed Inc.  
1337 W. Troy Street  
Ferndale, MI 48220

Dear Mr. Shweihat:

This letter concerns Nicotine Lollipops, which are currently marketed by your firm as shown on your Internet site, [www.whitelakecompounding.com](http://www.whitelakecompounding.com). This product is sold without a prescription. According to information on the Internet site, the product consists of nicotine combined with a natural sweetener and flavorings in a sugar-free base, and is available in 2 mg. or 4 mg. strengths. Your Nicotine Lollipops are intended as an aid for smoking cessation or to reduce nicotine addiction.

The intended uses noted above are conveyed through claims on your Internet site. These claims include statements such as "...Quit Smoking Now! With Nicotine Lollipops\*\*\* If your (sic) looking for a new way to quit smoking, Try our Nicotine Lollipops! \*\*\* Our Nicotine Lollipops contain FDA approved Nicotine Polacriflex and currently come in 2 strengths. The 2 mg strength is used for the average smoker and each 2 mg Nicotine lollipop is equivalent to one-half of a pack of cigarettes. For patients that smoke more than 2 packs a day, a 4 mg Nicotine Lollipop is available. \*\*\*The patient uses the lollipop when a craving occurs, and once the craving subsides, the patient simply places the lollipop back into the plastic container provided\*\*\*This unique dosage form not only allows the patient to get the nicotine when they want it, but it also mimics the hand to mouth habit many smokers develop. Each lollipop lasts approximately 4-5 smoking sessions\*\*\* 2mg 12 pack for 24.95\*\*\* 2 mg 36 pack 64.99\*\*\*4mg 12 packs for 34.95\*\*\*4mg 36 pack 84.99\*\*\*."

Based on the intended uses established by your Internet site, your Nicotine Lollipops are "drugs" as defined by section 201(g) of the Federal Food, Drug, and Cosmetic Act (the

Act). Although in the FDA Modernization Act of 1997, Congress provided certain conditions under which compounded drugs could be exempt from particular requirements of the Act, including sections 505 and 502(f)(1), as a result of a Supreme Court ruling last year, those exemptions are no longer available for compounded drugs.

Because of the Supreme Court decision, FDA determined that it needed to issue guidance on what factors it will consider in exercising its enforcement discretion regarding pharmacy compounding. This guidance issued on June 7, 2002 in the form of Compliance Policy Guide (CPG), Section 460.200. As a result, the agency now applies its longstanding policy to recognize and exercise its enforcement discretion for extemporaneous compounding, where reasonable quantities of drugs are manipulated upon receipt of valid prescriptions from licensed practitioners for individually identified patients. However, your Nicotine Lollipops do not qualify for enforcement discretion since you offer to sell the products without a prescription.

Your Nicotine Lollipops are also subject to Title 21 of the Code of Federal Regulations, (CFR) section 310.544. Under that regulation, they are a "new drug" as defined by section 201(p) of the Act. Under section 505(a) of the Act, a "new drug" may not be introduced or delivered for introduction into interstate commerce without an FDA-approved new drug application (NDA). We note that your Nicotine Lollipops are not the subject of an FDA-approved NDA and, therefore, they may not be marketed in the United States. The continued distribution of this product without an approved NDA violates section 505 of the Act.

In addition, your Nicotine Lollipops are misbranded within the meaning of section 502(o) of the Act in that they are manufactured in an establishment not duly registered under section 510 of the Act, and they have not been listed as required by section 510(j) of the Act. Section 510(g) exempts from the registration and listing provisions pharmacies that dispense prescription drugs upon the prescription of a licensed practitioner. Your firm, by contrast, compounds and sells Nicotine Lollipops without requiring prescriptions. The section 510(g) exemptions are therefore unavailable. The lollipops may also be misbranded under section 502(f)(1) of the Act on the grounds that their labeling fails to bear adequate directions for the uses for which they are being offered. They would not be exempt from this requirement under 21 CFR section 201.115 since they are unapproved new drugs. These products may also be misbranded under section 502(f)(2) of the Act in that their labeling fails to bear adequate warnings against use by children.

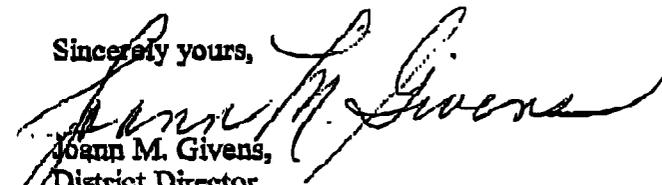
This letter is not intended to be an all-inclusive review of your Internet site and the products marketed by your firm. It is your responsibility to ensure that all drug products manufactured and distributed by your firm comply with federal laws and regulations. Federal agencies are advised of the issuance of all warning letters about drugs and devices so that they may take this information into account when considering the award of contracts.

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You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction.

We request that you reply in writing within fifteen (15) days of your receipt of this letter stating the action that your firm will take to discontinue marketing these drug products. Your response should be directed to Judith A. Putz, Compliance Officer, at the Detroit District Office of the U.S. Food and Drug Administration, 300 River Place, Suite 5900, Detroit, MI 48207.

Sincerely yours,



Joann M. Givens,  
District Director  
Detroit District Office

CC:

Melanie Brim, Director  
Michigan Board of Pharmacy  
611 West Ottawa Street  
P. O. Box 30670  
Lansing, MI 48909-8170  
(517) 373-2179 (FAX)