



DEPARTMENT OF HEALTH AND HUMAN SERVICE

13578J  
Food and Drug Administration  
New Orleans District  
Southeast Region  
6600 Plaza Drive, Suite 400  
New Orleans, LA 70127

Telephone: 504-253-4519  
FAX: 504-253-4520

June 27, 2002

**WARNING LETTER NO. 2002-NOL-34**

**FEDERAL EXPRESS**  
**OVERNIGHT DELIVERY**

Saiyid Rasheeq Wahid, M.D.  
1962 O'Neal Lane, Suite H-1  
Baton Rouge, Louisiana 70806

Dear Dr. Wahid:

On February 25 & 26, 2002, we inspected your firm, located at 1962 O'Neal Lane, Suite H-1, Baton Rouge, Louisiana, and found serious violations of Sections 502 and 505 of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and FDA's implementing regulations on the Internet through links in FDA's home page at <http://www.fda.gov>.

Your product "*Dr. Wahid's Herbal remedy an alternative medicine*" appears to be intended to treat, cure, or mitigate diseases, including AIDS and cancer. Evidence of the intended use of the product is that the label identifies it as "*an alternative medicine.*" Other evidence that your product is intended for use as a drug under the Act is that you require patients to sign a document that implicitly represents this product as an adjunct or alternative to other therapies for the disease(s) for which you are treating them (e.g. "*This offer is for patients that are diagnosed with a terminal illness only. I have \_\_\_\_\_ illness and have tried everything else and now taking this remedy. . . . I also feel that there is no other treatment that will help me.*"). Finally, in a brochure promoting the product, you state that it is "*working well*" on patients suffering from terminal illnesses such as AIDS, cancer, and hepatitis C; you also state that the product has helped patients suffering from other serious diseases, including lupus and arthritis. Based on the labeling of this product and its intended use, the product is a drug [Section 201(g)(1)(B) of the Act]. It is also a new drug [Section 201(p) of the Act] and may not be marketed legally in the United States without an approved New Drug Application [Section 505(a) of the Act].

The drug is also misbranded [Section 502(f)(1) of the Act] because the labeling fails to bear adequate directions for use. In addition, the labeling is false and misleading because it suggests that the product is safe and effective for its intended uses when, in fact, neither safety nor effectiveness has been established [Section 502(a) of the Act].

This letter is not intended to be an all-inclusive list of deficiencies in your product and its labeling. It is your responsibility to ensure adherence to each requirement of the Act and

regulations. You should review all 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 might 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 product.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. Once corrective actions have been taken, forward to this office documentation necessary to verify that corrections have been achieved. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time by which the corrections will be completed.

Address your reply to the U.S. Food and Drug Administration, Attention: Ms. Rebecca A. Asente, Compliance Officer, at the address above.

Sincerely,



Carl E. Draper  
District Director  
New Orleans District