



VIA FEDERAL EXPRESS

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

WARNING LETTER

FLA-00-18

January 4, 2000

Emilio Ruiz, CEO and Owner
PAL Laboratories, Inc.
10655 NW 29th Terrace
Miami, Fl 33172

Dear Mr. Ruiz:

During an inspection of your facility located at the above address on November 16 and 17, 1999, Investigator Jennifer M. Donzanti determined that you repack various OTC drug products, which products are human drugs within the meaning of section 201(g)(1)(b) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed that the drugs repacked by your firm are adulterated within the meaning of section 501(a)(2)(B) of the Act in that they are OTC drugs and the methods used in, or the facilities or controls used for, their manufacture, processing, packing or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice (GMP) regulations for drugs specified in Title 21 CFR, Part 211 as follows:

Failure of your firm to conduct stability studies or to have such studies conducted for you to justify the expiration dates that you use on the products you repack, or to have data demonstrating the container/closure system used by your firm is equal to or better than that used by the manufacturer, allowing use of the manufacturer's expiration date.

Failure to have written procedures covering the performance of a proper identity test on incoming drug products to be repacked to assure product is what it is purported to be.

Failure to have written procedures covering equipment/facilities cleaning or to validate the cleaning process to assure that all previous repacked batches were removed and that all cleaning materials were removed.

Failure to have or maintain a written procedure for handling complaints.

Emilio Ruiz
Page 2
January 4, 2000

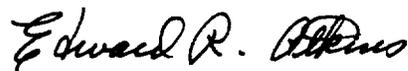
The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice regulations and all other regulations. Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts.

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.

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 being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to the Food and Drug Administration, Attention: Martin E. Katz, Compliance Officer, 555 Winderley Place, Maitland, Florida, 32751, telephone number 407-475-4729.

Sincerely,



Edward R. Atkins
Acting Director
Florida District