

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-97-09

December 4, 1996

Mr. Victor G. Farias
President, Proparna, Inc.
3307 N.W. 74th Avenue
Miami, Florida 33122

Dear Mr. Farias:

During an inspection of your firm on June 7-286, 1995, FDA Investigator Roy R. Rinc determined that you manufacture and repack a variety of prescription and over-the-counter (OTC) products, which are drugs within the meaning of Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

The products, "Spacol" liquid and tablets, contain atropine sulfate, hyoscyamine sulfate and scopolamine hydrobromide, and are labeled for use in the treatment of irritable bowel syndrome and duodenal ulcers. These products may not be introduced into interstate commerce under Section 505(a) of the Act since they are new drugs within the meaning of Section 201(p) of the Act and no approval of an application filed pursuant to Section 505(b) is in effect for such drugs.

The product, "Oti-Med" contains chloroxylenol, pramoxine hydrochloride and 10 mg Hydrocortisone, and is labeled as an antibacterial and antifungal agent for use in external auditory canal infections. These products may not be introduced into interstate commerce under Section 505(a) of the Act since they are new drugs within the meaning of Section 201(p) of the Act and no approval of an application filed pursuant to Section 505(b) is in effect for such drugs.

These products, as well as other products repacked by your firm are further misbranded within the meaning of Section 502(o) in that you have failed to file listing information as required by Title 21, Code of Federal Regulations, Part 207.20 (21 CFR 207.20).

Further, the above stated inspection revealed that drug products manufactured and repacked by your firm are adulterated within the

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meaning of Section 501(a)(2)(B) of the Act in that the methods used in, or the controls used for their processing, packaging or holding do not conform or are not operated or administered in conformity with the Current Good Manufacturing Practice (CGMP) Regulations to assure that your drugs meet the requirements of the Act as specified in 21 CFR 211, as follows:

Failure to have sufficient stability data for repacked drugs or document the existence of an adequate stability program; failure to maintain complete and adequate master or batch records covering both manufacturing and repacking operations; failure to have written procedures for cleaning and/or maintenance of equipment, nor are cleaning and use logs maintained; failure to perform adequate identity tests on all incoming bulk drug products and components; failure to have adequate label controls, including adequate identification of master labels, no SOP for proofing incoming labels, and access to labels not restricted; failure to maintain complete and adequate laboratory records or to have laboratory standards and equipment needed to perform necessary analysis; and, failure to have written procedures covering component handling or for retesting of raw materials over time.

We have received your responses dated July 21 and September 8, 1995, to the List of Observations left at your firm at the close of the inspection. Your corrective actions regarding the GMP violations listed above will be evaluated at the next inspection of your facility.

We understand that your firm has discontinued the manufacture and distribution of the product "Periavit Syrup" within the past year. For your information, "Periavit Syrup" contained cyproheptadine and was labeled for allergic reactions and as adjunctive therapy for anaphylactic reactions. As such, it would be considered a new drug and no approval of an application filed pursuant to Section 505(b) is in effect for such drugs. We are including this information should your firm decide to manufacture this product again. Please provide us with an estimate of the amount of product remaining in channels of distribution as well as stocks on hand or under the control of your firm, and your intentions regarding disposition of the product.

Other Federal agencies are routinely advised of Warning Letters issued so that they may take this information into account when considering the award of contracts. Additionally, pending applications for Agency approval (NDA, ANDA, SNDA, etc.) or export approval requests may not be approved.

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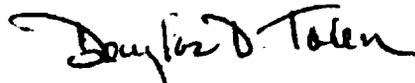
In order to facilitate the Food and Drug Administration (FDA) in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other Federal agencies concerning the award of government contracts, and to resume review of any pending applications, we request that you notify this office when corrective actions are completed and you believe your facility is in compliance with the GMP regulations so that a verification inspection can be scheduled.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all drug products you manufacture and repack are in compliance with the Act and the GMP regulations. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure and/or injunction, without further notice.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of specific steps you have taken to correct the new drug and misbranding violations. If correction cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to Martin E. Katz, Compliance Officer, Florida District, Food and Drug Administration, 7200 Lake Ellenor Drive, Ste. 120, Orlando, Florida 32809, telephone no. (407) 648-6823, ext. 262.

Sincerely,



Douglas D. Tolen
Director, Florida District