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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Refer to: CFN 1122528

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

August 19, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Richard P. Sowers, III
CEO and Chairman
Patient First Corporation
5000 Cox Road, Suite 100
Glen Allen, Virginia 23060

Dear Dr. Sowers:

The Food and Drug Administration (FDA) conducted an inspection of your drug repackaging facility on August 6, 1997. During the inspection, our investigator documented deviations from the Current Good Manufacturing Practice regulations (Title 21, Code of Federal Regulations (CFR), Parts 210 & 211). These deviations cause your liquid prescription drug products (Sulfatrim Pediatric Suspension, Antispasmode Elixir, and Q-Tuss HC) to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

1. Failure to assure that liquid drug products meet applicable standards of identity, strength, quality, and purity at the time of use, as the date applied to each product is not supported by appropriate stability data.
2. Failure to perform stability testing of the liquid drug products to appropriately determine storage conditions and expiration dates.
3. Failure to establish written procedures designed to assess the stability characteristics of the repackaged liquid drug products.
4. Failure to assure that the product containers and closures are suitable for their intended use, as they are not tested for conformance with all appropriate written procedures.

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The above listed violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal 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.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer. Mr. MacIntire can be reached at 804-379-1627, extension 14.

Sincerely,



Elaine Knowles Cole
Director, Baltimore District

cc: Virginia Board of Pharmacy
6606 West Broad Street
Richmond, Virginia 23230-1717