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DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
850 Third Avenue
Brooklyn, NY 11232

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Michel C. Lockhart
President & CEO
A.W. Curtis Pharmaceuticals, Inc.
319 Utica Avenue
Brooklyn, New York 11213

December 30, 1998

Ref.: NYK-1999-19

Dear Mr. Lockhart:

This letter concerns the marketing of "FORTEX Rubbing Oil". A.W. Curtis Laboratories, Inc., Detroit, Michigan, manufactures this product for your firm. The carton label for this product states that "FORTEX Rubbing Oil" contains methyl salicylate 40%, and peanut oil (linolenic acid).

A two page promotional/order sheet (labeling) titled "FORTEX Rubbing Oil...THE POWERFUL PAIN RELIEVER," states "FORTEX rubbing oil is a topical analgesic/anti-inflammatory medication...specially formulated peanut oil in the relief of pain and inflammation of arthritis...provides the clear and favourable benefit-to-risk ratio in the treatment of arthritis conditions over most oral anti-arthritic medications...Methyl salicylate is a well established medical compound in the topical treatment of pain and inflammation...The peanut oil has a high concentration of gamma linolenic acid (GLA), which is also well documented in medical research to possess the capability of inhibiting prostaglandins. By itself, this specially refined (unscented) peanut oil is a reliever of pain and inflammation...recommended for: Carpal tunnel syndrome... Diabetic neuropathy...Plantar fasciitis (Foot)..." This labeling also directs the consumer to soak extremities and the whole body in a solution of water and "FORTEX Rubbing Oil".

Other promotional material (labeling) titled "MEDICAL RATIONALE" states "This topical non steroidal anti-inflammatory preparation provides the effectiveness of its oral counterparts without associated side effects...Once Fortex rubbing oil is absorbed through the skin and hydrolyzed, its pharmacokinetic profile is similar to that of oral salicylic acid...Methyl salicylate bathing is one of the most effective methods of local salicylic acid application in rheumatology...(linolenic acid) is readily taken up by the skin and transported into the body..."

“FORTEX Rubbing Oil” is a drug [section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act)] and based on its formulation and intended uses, this product is an external analgesic drug. The safety and efficacy of this class of Over-the-Counter (OTC) drug is currently being evaluated by the Food and Drug Administration (FDA) under the OTC Drug Review. Pending the issuance of a final regulation, we do not object to the marketing of OTC drugs formulated and labeled in conformance with the proposed rule or were marketed in the United States before December 4, 1975, and do not present a danger to the health of the user. “FORTEX Rubbing Oil” is not formulated and labeled in accordance with the proposed rule for external analgesic drug products published in the February 8, 1983 **Federal Register**. Further, we do not have any information that shows your product, or any other similarly labeled and formulated OTC drug product, was marketed in the United States before December 4, 1975. We do not know of any evidence that “FORTEX Rubbing Oil” is generally recognized as safe and effective for its intended uses.

Based on the above, “FORTEX Rubbing Oil” is a new drug [Section 201(p) of the Act] which may not be legally marketed [Section 505 of the Act] because no application has been approved for this product [Section 505 of the Act]. Further, “FORTEX Rubbing Oil” is a new drug despite the status of the ingredients or labeling, because it is intended for transdermal absorption. This product is misbranded [Section 502(f)(1) of the Act] because its labeling fails to bear adequate directions for use.

The above list of violations is not intended to be an all inclusive list of deficiencies at your firm. It is your responsibility to ensure that all of your firm’s products meet all requirements of the Act and its implementing regulations. Federal agencies are advised on 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.

We request that you take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please 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. Your response should include an explanation of each step taken to prevent 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 corrections will be completed.

A.W. Curtis Pharm., Inc.
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Your response should be sent to Laurence D. Daurio, Compliance Officer, Food and Drug Administration, 850 Third Avenue, Brooklyn, New York 11232.

Sincerely,

A handwritten signature in black ink, appearing to read "Brenda J. Holman". The signature is written in a cursive style with a prominent loop at the end.

Brenda J. Holman
District Director