



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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Food and Drug Administration  
555 Winderley Place, Suite 200  
Maitland, Florida 32751

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-98-58

June 25, 1998

Mr. Brett J. Phillips, President  
Phillips Gulf Corporation  
8767 115th Avenue No.  
Largo, Florida 33773

Dear Mr. Phillips:

During an inspection of your facility located in Largo, Florida on December 9, 1997 to January 15, 1998, FDA Investigator Paul I. Figerole determined that you distribute Arth-Rx with Neurocaine topical lotion, which is labeled for conditions which cause it to be considered a drug within the meaning of Section 201 (g) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that the drugs you distribute are adulterated within the meaning of Section 501(a)(2)(B) of the Act, as follows:

1. Failure to adequately investigate 22 injury complaints received concerning Arth-Rx.
2. Failure to properly segregate recalled products from products held for sale.
3. Failure to have or assure there are written procedures for:

Handling of complaints;  
Handling of recalled or returned product;  
Warehousing and distribution of drug products; and,  
Approval or rejection of drug products manufactured for your firm by another company, including identification of the person or persons responsible for such approval or rejection.

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In addition, two lots of Arth-Rx are also adulterated within the meaning of section 501(c) in that they have been shown by FDA analysis to contain 130-150% of the declared capsaicin.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. Please refer to the Form FDA 483, which was left with you by the investigator at the close of the inspection.

You should take prompt action to correct these violations. Failure to promptly correct these violations 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, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations and to prevent the recurrence of similar violations. Please include in your response your intentions regarding the two lots found by analysis to be superpotent. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which corrections will be completed.

Your response should be sent to the Food and Drug Administration, Orlando District Office, 555 Winderley Place, Maitland, Florida 32751, Attention: Martin E. Katz, Compliance Officer.

Sincerely,



Douglas D. Tolen  
Director, Florida District