

September 15, 1997

WARNING LETTER
CHI-46-97

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Henry H. Hoyt, Jr.
Chairman of the Board and
Chief Financial Officer
Carter-Wallace, Inc.
1345 Avenue of the Americas
New York, New York 10105

Dear Mr. Hoyt:

During an inspection of your Wallace Laboratories facility located at 434 North Morgan Street, Decatur, Illinois, conducted August 18, 19, 20, 21, 25 and 28, 1997, FDA Investigator Roger J. Adams documented deviations from the current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Parts 210 & 211). These deviations cause your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, Cosmetic Act, as follows:

1. Failure to fully justify, with the development and retention of appropriate data, the increase of batch size of "Evict Liquid Wormer" from [REDACTED] liters to [REDACTED] liters.
2. Failure to have written procedures for the disposition of the products "Evict" and "Lassie" after clearance of the holding tank transfer line.
3. Failure to assure that all employees follow all written production and packaging procedures.
4. Failure to document equipment cleaning processes to assure that all equipment is appropriately and properly cleaned.

We note that labeling for the Evict Liquid Wormer and Lassie Liquid Wormer products contains the phrase "ANADA No. [REDACTED], Approved by FDA." You should be aware that any language or wording on product labeling or literature that implies and suggests FDA approval for your products is prohibited under Section 301(l) of the Federal Food, Drug and Cosmetic Act.

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The above identification of violations is not intended as 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. Until these violations are corrected, Federal agencies will be informed that FDA Chicago District recommends against the award of contracts for affected products.

You should ensure that prompt action is taken to correct the deviations noted during the inspection. Failure to adequately correct these deviations may result in regulatory actions without further notice. Other possible regulatory actions may include seizure and injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific actions you intend to take or have taken to correct the 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, please state the reason for the delay and the timeframe within which the corrections will be completed.

Your reply should be sent to the attention of Richard Harrison, Acting Director, Compliance Branch.

Sincerely,

¹⁵¹
Raymond V. Mlecko
District Director

Enclosure: Form FDA 483

cc: Mr. Lawrence D. Hearn, Director
Pharmaceutical Manufacturing
Wallace Laboratories
434 North Morgan Street
Decatur, Illinois 62523