



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

g1240d

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

May 11, 2001

Ref: 2001-DAL-WL- 23

WARNING LETTER

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Carlton E. Turner, Ph.D., D.Sc.
President/CEO
Carrington Laboratories, Inc.
2001 Walnut Hill Lane
Irving, Texas 75038

Dear Dr. Turner:

On April 16/20, 2001, an FDA investigator conducted an establishment inspection of your OTC drug manufacturing operations for topical liquids, ointments, and creams. These products meet the definition of drugs under Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

During the inspection, the investigator documented significant deviations from the Current Good Manufacturing Practice for Finished Pharmaceuticals - Title 21, Code of Federal Regulations, Parts 210 and 211 (CGMP). These deviations cause your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Act. A drug is adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practices.

At the completion of the inspection, the investigator issued Form FDA 483 (Inspectional Observations) listing significant deviations from CGMP as follows:

- Failure to perform validation of manufacturing processes to ensure that the procedures, when used, will consistently result in purported or expected product quality [21 CFR 211.110(a)].
- Failure to perform validation of the rework procedure for non-conforming drug product batches [21 CFR 211.115].

Page 2 – Dr. Carlton E. Turner, President/CEO
Carrington Laboratories, Inc.
May 11, 2001

- Failure to validate the cleaning procedures for drug product manufacturing and packaging equipment [21 CFR 211.67].
- Failure to perform appropriate laboratory determination for conformance to final specifications of each batch of drug product prior to release [21 CFR 211.165].
- Failure to perform validation of drug product analytical methods [21 CFR 211.165(e)].
- Failure to have stability data to support drug product expiration dates [21 CFR 211.166] and failure to ensure that all drug products bear appropriate expiration dating [21 CFR 211.137].
- Failure to qualify processing equipment used in drug stability studies, and testing equipment used for microbiological testing of OTC drugs [21 CFR 211.68(a)].
- Failure to follow established written procedures designed to ensure drug product quality [21 CFR 211.100(b)]. For example, scheduled preventative maintenance of the purified water system has not been documented in the last two years.
- Failure to have documentation of annual product evaluations [21 CFR 211.180(e)].

The observations listed on the Form FDA 483 are not intended to be an all-inclusive list of the violations and deficiencies that may exist at your firm. It is your responsibility to ensure all requirements of the Act, and regulations promulgated thereunder, are being met. Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts.

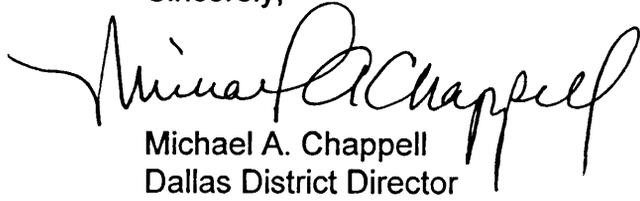
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction.

You should 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, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective actions

Page 3 – Dr. Carlton E. Turner, President/CEO
Carrington Laboratories, Inc.
May 11, 2001

cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed. Please direct your response to James R. Lahar, Compliance Officer at the above address.

Sincerely,



Michael A. Chappell
Dallas District Director

MAC:jrl