



DEPARTMENT OF HEALTH & HUMAN SERVICES

PURGED

Public Health Service

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Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

June 17, 1999

WARNING LETTER

cc: HFI-35
DWA

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 99-35

Mr. Bruce Pindyck
Chairman and CEO
Meridian Industries, Inc.
100 East Wisconsin Avenue
Suite 2750
Milwaukee, Wisconsin 53202

Dear Mr. Pindyck:

During our inspection of your Kleen Test Products, over-the-counter (OTC) drug manufacturing operation, located in Milwaukee, Wisconsin, our investigators found serious violations of the Current Good Manufacturing Practices (GMPs) for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Part 211 (21 CFR 211). Your repacked OTC drug products are adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

The violations observed during our inspection include but are not limited to the following:

1. Failure to reject material that did not meet specifications [21 CFR 211.84(e)]. In that the initial potency testing of samples from lots 61, 62, and 63 were found to be out of specification (subpotent).
2. Failure to withhold from use each lot each lot of components, drug product containers, and closures until the lot has been sampled, tested, or examined, as appropriate, and released for use by the quality control unit [21 CFR 211.84(a)]. In that there is no documentation of any potency testing for lot 64 of the antibacterial baby wipe solution. Lot 64 has been released and used in the production of the final product.

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3. Failure to thoroughly investigate the failure of a batch to meet any of its specifications [21 CFR 211.192]. In that several lots of the antibacterial baby wipes had pH results below specifications and the products were released with no explanation.
4. Failure to determine the percentages of theoretical yield at the conclusion of each appropriate phase of manufacturing, processing, packaging, or holding of the drug product [21 CFR 211.103]. In that percentages of theoretical yield are not determined at the conclusion of packaging.
5. Failure to calibrate instruments, apparatus, gauges, and recording devices at suitable intervals in accordance with an established written program containing specific directions, schedules, limits, and provisions for remedial action in the event accuracy and/or precision limits are not met [21 CFR 211.160(b)(4)]. In that pH readings are not being documented and your standard operating procedures (SOP) do not contain provisions for documenting pH readings.

The above indication of violations is not intended to be 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. Federal agencies are advised of the issuance of all Warning Letters about drugs so 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. This is official notification that FDA expects all your locations to be in compliance.

In addition, 21 CFR 211.137(h) states that human OTC drug products that do not bear dosage limitations may be exempt from the expiration dating regulation, if the product is stable for at least three years as supported by appropriate stability data.

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, including an explanation of each step being taken to prevent the 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 the corrections will be completed.

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Your reply should be sent to Compliance Officer Carrie A. Hoffman at the address on the letterhead.

Sincerely,

A handwritten signature in black ink, appearing to read "James A. Rahto". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

James A. Rahto
District Director
Minneapolis District

CAH/rfk

cc: Bill Crouch
President
Kleen Test Products
8225 W Parkland Ct
Milwaukee, WI 53723