



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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**PURGED** RAK

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

November 2, 1999

xc: HFI-35  
DWA

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

**Refer to MIN 00 - 06**

David D. Goldberg  
Chief Executive Officer  
Goldberg Consulting LLC  
4525 Hiawatha Avenue  
Minneapolis, Minnesota 55406

Dear Mr. Goldberg:

During our inspection on September 27-28, 1999, and October 1, 4-6, 8, 1999, of your over-the-counter (OTC) drug manufacturing facility, Allied International Laboratories, located in Minneapolis, MN, 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 OTC drug products are adulterated within the meaning of Section 501(a)(2)(B) of the Act.

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

1. Failure to have appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, for each batch of drug product, prior to release [21 CFR 211.165(a)] in that finished product is sometimes released prior to completion of finished product testing.
2. Failure to have all drug product production and control records reviewed and approved by the quality control unit to determine satisfactory conformance with all established, approved written procedures before a batch is released or distributed [21 CFR 211.192] in that there is no documentation of the QC/QA approval for release of finished product for shipment.

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3. Failure to test each component for conformity to all appropriate written specifications for purity, strength, and quality [21 CFR 211.84(d)(2)] in that there is no identity and purity testing of each lot of incoming raw ingredients.
4. Failure to calibrate instruments, apparatus, gauges, and recording devices at suitable intervals in accordance with an established written program containing specific directions, schedules, limits for accuracy and precision [21 CFR 211.160(b)(4)] in that there are no calibration and maintenance records for the HPLC and GC used to analyze the active ingredients.
5. Failure of your laboratory records to include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations [21 CFR 211.194(a)] in that your laboratory records lack the following: description of the sample (location from where the sample was obtained), quantity, date sample was taken, date sample was received, statement of the method used for analysis, record of all calculations performed including units of measure and conversion factors, and the initials or signature of a second person showing the original records have been reviewed for accuracy, completeness and compliance with established standards.

The above indication of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure 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 the Food and Drug Administration expects all your locations to be in compliance.

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 stylized with a large initial "J" and a long horizontal stroke extending to the right.

James A. Rahto  
Director  
Minneapolis District

CAH/ccl