



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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PURGED

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

April 2, 1999

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 99 - 23

Michael G. Guy
President
Guy & O'Neill, Inc.
617 Tower Drive
Fredonia, WI 53021

Dear Mr. Guy:

During our inspection of your Guy & O'Neill drug manufacturing facility located at 340 South Milwaukee Street, Fredonia, WI, 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 over-the-counter (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 determine actual yields and 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 no calculation of actual versus theoretical yield is performed.

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2. Failure to assure that your drug product meets applicable standards of identity, strength, quality, and purity at the time of use by bearing an expiration date determined by appropriate stability testing (21 CFR 211.137) in that you have no data to support the five-year expiration date on Skeeter Stik.
3. Failure to establish scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity [21 CFR 211.160(b)] in that no documentation exists to support your policy of testing 
 per batch of Skeeter Stik for final release specifications.
4. Failure to assure batch uniformity and integrity of drug products by following written procedures that describe the in-process controls and tests to be conducted on appropriate samples of in-process materials of each batch [21 CFR 211.110(a)] in that in-process weight checks are not being followed. Your procedures require a measurement every 
 and often a much greater length of time passes between measurements.

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.

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,

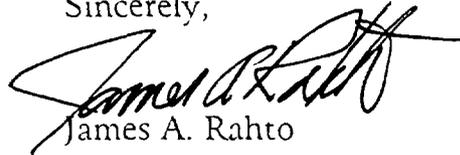
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including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days state the reason for the delay and the time within which the corrections will be completed.

Due to the serious and continuing nature of the violations, we believe it is imperative to have a meeting to discuss the violative regulatory history of your firm. We have scheduled time on Friday, April 9, 1999, at 1:00 P.M. at our Minneapolis Office. If this time conflicts with a prior engagement, please contact Compliance Officer Carrie A. Hoffman at 612-334-4100 ext. 159 to arrange an acceptable day and time. Your reply to this Warning Letter should also 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", with a stylized flourish extending from the end of the name.

James A. Rahto
Director
Minneapolis District

CAH/ccl