



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service

Food & Drug Administration
1141 Central Parkway
Cincinnati, OH 45202-1097

May 5, 1998

**WARNING LETTER
CIN-WL-98-256**

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Frank J. Martinek, President/Owner
Mid-America Chemical Corp.
4701 Spring Street
Cleveland, Ohio 44131

Dear Mr. Martinek:

During a Food and Drug Administration inspection on April 1/6, 1998, of your drug manufacturing facility located at the above address, our investigator documented serious deviations from the Current Good Manufacturing Practices Regulations (Title 21 Code of Federal Regulations, Parts 210 and 211). These deviations cause your drug product, Steril-Touch hand sanitizer packaged in 55 gallon plastic drums to be adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

The deviations observed include:

Failure to assure that each batch of drug product conforms to established specifications.

There are no written specifications for the hand sanitizer. There is no written descriptions of the hand sanitizer to include such things as the formula of the product for use in production and the list of components used in the product. Finished product testing is not documented in that no laboratory records or test results are maintained. The active ingredient, ethyl alcohol is labeled: "FOR INDUSTRIAL USE ONLY". A certificate of analysis is received for the ethyl alcohol but no further testing is performed on the ethyl alcohol by your firm.

Failure to establish and maintain a master production and control record for the drug product in order to assure uniformity from batch to batch.

A master production record for the production of the hand sanitizer has not been established. There are no established manufacturing and control instructions, sampling and testing procedures, specifications, and precautions to be followed in the manufacturing of the hand sanitizer.

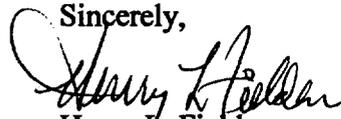
The above described violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that you adhere to all current regulations applicable to your operations. Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these violations. Failure to achieve prompt correction may result in regulatory action without further notice. These include seizure and/or injunction.

Please advise us in writing within fifteen (15) working days of receipt of this letter of the specific actions you are taking to correct these violations. Your response should explain each step you have taken to correct the noted violations, including steps taken to prevent recurrence of similar violations. Include any documentation showing these corrections. 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.

Your reply should be sent to the U.S. Food and Drug Administration, 1141 Central Parkway, Cincinnati, Ohio 45202-1097, to the attention of Evelyn D. Forney, Compliance Officer. Any questions regarding this letter may be directed to Mrs. Forney at telephone no. (513) 684-3501 extension 163.

Sincerely,



Henry E. Fielden
Acting District Director
Cincinnati District

Failure to establish and maintain adequate batch production and control records for each batch of hand sanitizer including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished at the time of performance. No records are kept of any of the significant steps performed during the manufacturing process.

Failure to have any information which would establish stability for the intended period of use of the hand sanitizer.

There is no written testing program designed to assess the stability characteristics of the hand sanitizer and no stability tests have been performed. No determination of an appropriate expiration date for the hand sanitizer has been established to assure that the drug product meets applicable standards of identity, strength, quality, and purity at the time of use.

Failure to record distribution by lot number in a manner which would permit prompt recall. Lot numbers which are placed on each drum of finished product of hand sanitizer are not recorded on distribution records. There are no written procedures describing the distribution of the drug product. In addition, there are no written warehousing procedures.

Failure to establish and follow written procedures for production and process controls covering all aspects of the hand sanitizer manufacturing procedure designed to assure that the drug product has the identity, strength, quality, and purity it purports or is represented to possess.

For example, there are no written procedures describing receipt and storage of drug components; no written procedures for testing and approval or rejection of raw materials; no written procedures describing reprocessing of finished product; and no written procedures describing finished product testing and release for distribution.

Failure to establish and follow written procedures describing the handling of all written and oral complaints regarding the hand sanitizer.

Failure to establish adequate written procedures assuring that the correct labels and labeling are used for the hand sanitizer.