



DEPARTMENT OF HEALTH & HUMAN SERVICES

*Product*  
*FJ*

HFJ-35  
M216N

Public Health Service  
Cincinnati District

Food & Drug Administration  
6751 Steger Road  
Cincinnati, OH 45237-3097

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

October 14, 1998

WARNING LETTER  
CIN-WL-98-377

Kenneth W. Braund, President  
Steril-Touch Limited  
8080 Hermitage Road  
Concord, Ohio 44077

Dear Mr. Braund:

We are writing to you because during an inspection of your firm located at the above address by the Food and Drug Administration (FDA) on July 20 /August 24, 1998, our Investigator collected information that revealed serious regulatory problems involving SANI-HAND INSTANT HAND SANITIZER which is manufactured and distributed by your firm.

Under the the Federal Food, Drug, and Cosmetic Act (the Act), this product is considered to be a drug. The law requires that manufacturers of drug products conform with the requirements of the Current Good Manufacturing Practice (GMP) Regulations as specified in Title 21, Code of Federal Regulations (CFR), Parts 210 and 211.

The inspection revealed that your drug product is adulterated within the meaning of section 501(a)(2)(B) of the Act, in that the methods used in, or the facilities or controls used for the manufacture, processing, packing, storage or distribution are not in conformance with the requirements of the Current Good Manufacturing Practice Regulation as follows:

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

The bulk incoming sanitizer product which is repackaged is not tested to determine conformance with appropriate specifications for identity and strength and your firm does not receive a certificate of analysis from the component manufacturer. There is no finished product testing performed and there is no test data to document antimicrobial claims made for your hand sanitizer.

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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. Your firm has no stability testing data to support the expiration date on the hand sanitizer label.

Failure to have written procedures describing the distribution of drug products.

There are no procedures in place whereby the oldest approved stock of your drug product is distributed first. There is no procedure establishing a system by which the distribution of each lot of your drug product can be readily determined to facilitate its recall if necessary.

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.

There are no written procedures describing the drug repacking process including finished product testing procedures; the receipt, identification, storage, handling, sampling, testing, and approval or rejection of components and drug product containers and closures; and the assignment of lot numbers and expiration dates. There are no established specifications for the hand sanitizer.

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

Your firm does not maintain a complaint file. Written procedures describing the handling of all written and oral complaints regarding your drug product have not been established.

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

There are no written procedures describing the receipt, identification, storage, handling, sampling, examination, and/or testing of labeling and packaging materials.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the FDA inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality

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assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems you must promptly initiate permanent corrective actions. 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 being initiated by The Food and Drug Administration without further notice. Possible actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (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 action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response to this Warning Letter should be sent to Evelyn D. Forney, Compliance Officer, Food and Drug Administration, 6751 Steger Road, Cincinnati, Ohio 45237.

Sincerely,

A handwritten signature in black ink, appearing to read 'R. Duane Satzger', with a stylized flourish at the end.

R. Duane Satzger, Ph.D.  
Acting District Director  
Cincinnati District