



DEPARTMENT OF HEALTH & HUMAN SERVICES

Redacted
H
M 2104N
HFI-35
Public Health Service
Cincinnati District

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

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

September 30, 1998

WARNING LETTER
CIN-WL-98-393

John A. Giltinan, President
Gebauer Company
9410 St. Catherine Avenue
Cleveland, Ohio 44104

Dear Mr. Giltinan:

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 Ethyl Chloride Topical Anesthetic Skin Refrigerant 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 medical device. The law requires that manufacturers of medical devices conform with the requirements of the Quality System Regulation (QSR) as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that the device is adulterated within the meaning of section 501(h) 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 Quality System Regulation as follows:

Failure to ensure that finished devices meet all specifications prior to distribution.

Lot # 819 of finished product Ethyl Chloride, U.S.P. Topical Anesthetic Skin Refrigerant was released for distribution even though the product was known to have a foul odor. The foul odor was observed in the product by your filling line personnel and your firm failed to conduct an odor test as required by the U. S. Pharmacopeia, Vol. 23 (USP 23) monograph for Ethyl Chloride, U.S.P. and your firm's written test procedure for Ethyl Chloride, "Non-Volatile residue Test" (T-013.4) dated 11/21/97. The filling line personnel reported the

Page 2
October 1, 1998

observation of the foul odor to the Quality Control Manager prior to distribution of the product. The U.S.P. 23 monograph for Ethyl Chloride states that the limit for odor in the product is that no foreign odor should be perceptible.

Failure to adequately ensure that the use of nonconforming products are closely monitored and does not become accepted practice.

Ethyl Chloride, U.S.P. Topical Anesthetic Skin Refrigerant, Lot # 819 which had a foul odor was released for distribution by your firm. The disposition and justification for release of the nonconforming products was not documented. Justification for release of the nonconforming product was not based on scientific evidence. An investigation into the cause of the nonconforming product was done only after complaints were received by your firm concerning a foul odor in the Ethyl Chloride Topical Anesthetic Skin Refrigerant, Lot # 819 which was in distribution. Between May 1998 and July 1998 twenty (25) complaints were received.

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 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 devices so that they may take this information into account when considering the award of contracts. Also, no requests for Certificates For Products For Export will be approved until the violations related to the subject devices have been corrected.

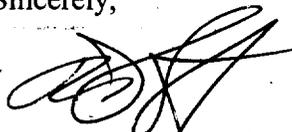
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by The Food and Drug Administration without further notice. Possible actions include, but are not limited to, seizure, injunction, and/or civil penalties.

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.

Page 3
October 1, 1998

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 be "R. Duane Satzger", written over a horizontal line.

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