



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region *g1678d*

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6004

August 28, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mark Newman, President and Owner
Sonar Products, Inc.
609 Industrial Road
Carlstadt, New Jersey 07072

FILE NO.: 01-NWJ-35

Dear Mr. Newman:

On July 18 through July 31, 2001, the U.S. Food and Drug Administration conducted an inspection of your facility located at 609 Industrial Road, Carlstadt, New Jersey. During the inspection our investigator documented significant deviations from the Current Good Manufacturing Practices Regulations (cGMPs) Title 21, Code of Federal Regulations, Part 210 and 211, in conjunction with your firm's manufacture of Prescription and Over-the-Counter (OTC) drug products.

The inspection revealed that drug products manufactured at your facility are adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the methods used in, or the facilities or controls used for their manufacture, processing, packing, or holding do not conform with cGMPs, to assure that such drug products meet the requirements of the Act. The deviations were presented to you on a FDA-483, List of Inspectional Observations, at the close of the inspection on July 31, 2001.

The significant observations are as follows:

1. Your firm has not validated the analytical methods used for in-process, stability, and finished product testing for the drug products [REDACTED]

Additionally, your firm has not completed the analytical method validation for the drug products [REDACTED]

2. Your firm fails to perform assay testing for all three active ingredients, [REDACTED], contained in the topical prescription drug product [REDACTED]. Your firm conducts assay testing for only one of ingredients, [REDACTED], and does not test for [REDACTED] and [REDACTED].
3. Your firm does not perform Preservative Effectiveness Testing as part of your release testing and stability program for all prescription and OTC drug preparations.
4. Failure to follow Standard Operating Procedure (SOP)-007-15 "Acceptable Testing Time Intervals", which states stability samples are to be tested within 60 days of their scheduled pull date. Your Stability Testing Log documented a total of 67 out of 378 stability samples that did not meet the 60-day testing timeframe since August 2000.
5. Your firm failed to store all finished drug products and raw materials within the specified ranges of 59° and 86° F as set forth in your SOP-001-07 "Storage Conditions of Finished Goods". For Example:
 - a. On July 23, 2001, the temperature chart recorder in your Manufacturing and Storage Area was observed at 90° F and on four other dates, June 18, June 25, July 9, and July 16, 2001, the temperature was recorded above the maximum of 86° F.
 - b. On numerous occasions the temperature in the Retain/Stability Room, where raw materials are stored, exceeded 86° F within the last two months.

In addition, during the inspection there were questions raised by the Investigator concerning your cleaning procedures for non-dedicated holding drums. We reviewed your new SOP for Cleaning of Blue Holding Drums and it appears adequate. We recommend you conduct a comprehensive evaluation of your firm's cleaning procedures for all equipment.

We received your response letter dated August 8, 2001, regarding the inspectional observations noted on the FDA-483. We will review the implementation and the adequacy of your corrective actions during our follow-up inspection of your firm. We will schedule a follow-up inspection as soon as you inform us that all cGMP deficiencies have been corrected.

Sonar Products, Inc.
Carlstadt, New Jersey 07072

Warning Letter 01-NWJ-35

The above identification 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 Practices Regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs and devices 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 without further notice. This includes seizure and/or injunction.

You should notify this office in writing within 15 working days of receipt of this letter, of any additional corrective actions, including an explanation of each step being taken to prevent the recurrence of similar conditions. If corrective action cannot be completed within 15 working days, state the reason for the delay and the timeframe within which corrections will be completed. Your reply should be sent to the Food and Drug Administration, New Jersey District Office, 10 Waterview Blvd, 3rd Floor, Parsippany, New Jersey 07054, Attention: Andrew Ciaccia, Compliance Officer.

Very truly yours,

Edmund H. Wilkins, Sr.
DOUGLAS I. ELLSWORTH
District Director
New Jersey District Office

AC:slm