



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Mid-Atlantic Region

D 112 B

Telephone (201) 331-2904

January 17, 1997

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

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Richard M. Kleim, President & CEO
Sybron Chemicals, Inc.
Birmingham Road
Birmingham, New Jersey 08011

RELEASE

REVIEWED BY AC
C.O.

1/23/97
DATE

FILE NO.: 97-NWJ-17

Dear Mr. Kleim:

This is regarding an inspection of your facility located Birmingham Road, Birmingham, New Jersey by the U.S. Food and Drug Administration between the dates of December 10 through December 16, 1996. During the inspection our investigator documented serious deviations from the current good manufacturing practice regulations (Title 21, Code of Federal Regulations, Part 210 and 211) in conjunction with your firm's manufacture of active pharmaceutical ingredients ("API", formerly referred to as bulk pharmaceutical chemicals).

These deviations were presented to your attention on an FD-483 List of Observations at the close of the inspection on December 16, 1996. The CGMP deficiencies cause your products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act.

The significant observations are as follows:

1. Sybron Chemicals failed to validate the consistency of the manufacturing process to include intermediate on-site processing, the impact of off-site contracted drug processing, and to assure the drug has the identity, strength, quality and purity that it claims to process.
2. Failure to validate the effectiveness of the cleaning procedures used for in-process manufacturing equipment and/or document the absence of contaminants from off-site contracted product drier services.
3. Failure to establish product purity specifications and to test for impurities such as process contaminants and degradents.

4. Failure to implement appropriate statistical quality control criteria for sampling, testing, and batch release, based on representative in-process and finished product samples.
5. Failure to incorporate batch record review as a finished product release criteria and to retain records to document finished product release by the Quality Control Unit.
6. Failure to test the purity and quality of the on-site well water used as an in-process component in the manufacture of a drug component.
7. Failure to develop a written stability program for the product Sodium Polystyrene Sulfonate, to include samples size, storage conditions, sample container closure system. The firm also failed to have a validated analytical test procedure and assays that documented stability indicating for this U.S.P. product.

We have received your response letter dated January 2, 1997, regarding the inspectional observations made on the FD-483. We have reviewed your response and we consider your intended corrective actions to be adequate. We will confirm their adequacy during our next FDA inspection.

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. We recommend that you conduct a complete evaluation of your facility for CGMP compliance.

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.

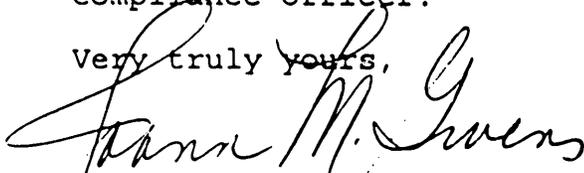
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This includes seizure and/or injunction.

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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,


JOANN M. GIVENS
Acting District Director
New Jersey District Office

AC:slw