



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region 20521

Telephone (973) 526-6004

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

December 12, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

William Neuberg
Owner
Shamrock Technologies, Inc.
117 Docks Corner Road
Dayton, New Jersey 08810

FILE NO.: 02-NWJ-13

Dear Mr. Neuberg:

On October 24, 25, 29 and 31, 2001, the U.S Food and Drug Administration conducted an inspection of your facility located at Foot of Pacific Street, Newark, 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 veterinary drug products.

The inspection revealed that veterinary 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 October 31, 2001.

The significant observations are as follows:

1. No assurance that the veterinary drug products Androhep Plus and Androhep Lite are not contaminated with various industrial products. Your firm manufactures waxes, polyterafluoroethylene and polyethylene/polytetrafluoroethylene mixes for the Ink and coating industries in the same blender, [REDACTED], as the above referenced veterinary drug products. Your firm does not have validated cleaning procedures for Androhep Plus and Androhep Lite and does not perform any testing on the veterinary drug products for the presence of industrial products.

**Shamrock Technologies, Inc.
Newark, New Jersey 08810**

**Warning Letter
December 7, 2001**

- 2. The manufacturing process for the products Androhep Plus and Androhep Lite is not validated. Your firm has no documentation to support the manufacturing parameters, the order and amount of components, and blending time used to manufacture the finished veterinary drug products.**
- 3. Your firm fails to perform any testing or receive a Certificate of Analysis (COA) to verify the identity of the active raw materials, Gentamicin Sulfate and Neomycin Sulfate, which are used in the manufacture of the finished veterinary drug products Androhep Plus and Androhep Lite.**
- 4. Failure to store the finished product Androhep Plus and Androhep Lite (100 kg drums), as per the temperature conditions stated on the product label. The product label states "Store at 2-8 °C". The finished product was stored at room temperature [REDACTED] for 3 to 4 days prior to shipping.**
- 5. The raw materials used for the products Androhep Plus and Androhep Lite are not to be used in the manufacture of drug products. The COA for the Gentamicin Sulfate (faxed to your firm at the request of our investigator) states "For research use only" and "Not for human or drug use" and the Safety Information for the Base Powder, Buffer AP, states "MAY CAUSE HARM TO THE UNBORN CHILD" and "MAY CAUSE CONGENITAL MALFORMATION IN THE FETUS".**

We received your firm's letter dated October 25, 2001, which states "Shamrock Technologies will not produce any API or drug products in its Newark Plant". We have placed this letter in our establishment files. Based on the letter we are canceling your drug registration. If in the future you intend to manufacture any pharmaceutical drug products, including veterinary drugs, you must file for registration and comply with each requirement of the current Good Manufacturing Practice Requirements.

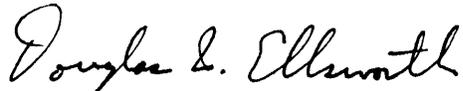
The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts. If you continue to produce any APIs or drug products, you must 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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Warning Letter
December 7, 2001

If you intend to produce any API's or drug products, you should notify this office in writing within 15 working days of receipt of this letter, of any 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. 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,



Douglas I. Ellsworth
District Director
New Jersey District Office

AC:slm