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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Refer to: CFN 1124900

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

June 25, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Ram Javia, Chief Executive Officer
UniGen Pharmaceuticals, Inc.
1221 Tech Court
Westminster, Maryland 21157

Dear Mr. Javia:

The Food and Drug Administration (FDA) conducted an inspection of your Westminster, Maryland facility on May 19-27, 1998. During the inspection, deviations from the Current Good Manufacturing Practice Regulations (CGMP), (Title 21, Code of Federal Regulations (CFR), Parts 210 & 211), were observed. The following deviations cause your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act):

1. Failure to establish and follow written procedures for production and process controls designed to assure that drug products have the identity, strength, quality, and purity they purport to possess, in that production processes have not been validated for Acetaminophen Children's Oral Suspension, Quadratus Pediatric Suspension, and Guaifenesin, NR Liquid drug products. For example:
 - a. There was incomplete production and process validation documentation regarding acceptable mixing speeds, mixing times, hold time prior to fill, fill volume, and equipment cleaning.
 - b. There was no installation or operational qualification for the [REDACTED]-gallon stainless steel tank identified as TK1 used for mixing in-process and finished drug products.

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2. Failure to establish adequate written production and process control procedures covering all critical aspects of manufacturing operations. For example:
 - a. Failure to establish sampling and testing plans which have acceptance criteria to assure that sampling and testing is based on appropriate statistical quality control criteria.
 - b. Failure to establish adequate procedures for the testing of in-process suspensions after storage for long periods of time (i.e., up to 16 hours).
 - c. Failure to establish adequate equipment cleaning procedures.
 - d. Failure to establish adequate instrument calibration procedures which contain specific directions.
 - e. Failure to establish adequate labeling issuance procedures which reconcile the quantities of labeling issued, used, and returned.
 - f. Failure to establish written distribution procedures.
 - g. Failure to establish written procedures for handling written and oral complaints regarding drug products.
 - h. Failure to establish adequate written storage procedures to assure that drug products are stored under appropriate temperature conditions.
3. Failure to maintain adequate reserve samples consisting of twice the quantity necessary for all tests required to determine that drug products meet all specifications.
4. Failure to maintain adequate and complete master production and control records which include the maximum and minimum theoretical yields.

The above listed violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal 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

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when considering the award of contracts. Additionally, pending NDA, ANDA, or export approval requests may not be approved until the aforementioned violations are corrected.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Northern Virginia Resident Post, 101 West Broad Street, Suite 400, Falls Church, Virginia 22046, to the attention of Gerald W. Miller, Compliance Officer. Mr. Miller can be reached at 703-235-8440, extension 504.

Sincerely,



Elaine Knowles Cole
Director, Baltimore District