



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Orleans District Compliance

HF1-35
(Jurg & RAA)

4298 Elysian Fields Avenue
New Orleans, LA 70122

D1176 B

February 7, 1997

WARNING LETTER NO.97-NOL-31

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. J. Richard Cook, President
Medco Pharmaceuticals, Inc.
P.O. Box 2088
Covington, Louisiana 70434

Dear Mr. Cook:

During an inspection of your facility, located at 2015 Highway, 190 Bypass, Covington, Louisiana, our investigator documented deviations from the Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Part 211) regarding your firm's pharmaceutical manufacturing operation. These deviations cause your products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection, during December 9-13, & 16, 1996 through January 2, 3, 6, 8-10, & 17, 1997, revealed the following objectionable conditions: failure to adequately validate the manufacturing process for your drug products; failure to adequately document radiation sterilization validation of container-closure components; failure to adequately ensure the integrity of the packaging used for sterile container-closure components; failure to adequately validate your current environmental monitoring plan; failure to establish a valid rationale for your current preservative effectiveness testing procedure; failure to include in your stability program an adequate number of batches for all products; failure to specify an adequate sample size for the sterility testing of stability samples; failure to audit vendors, as required in your procedures, or to establish adequate monitoring procedures in place of vendor audits; failure to include in your media fill procedure and microbiological assay of incoming raw ingredient procedure an adequate follow-up investigational plan in response to contamination; failure to include in your environmental monitoring procedure adequate assurance of differential air pressure maintenance between shift start-up and conclusion and an adequate follow-up investigational plan in response to out-of-specification

contamination levels; and, failure to maintain a master file for your Tetrahydrozoline HCL Eye Drop formula containing Zinc Sulfate.

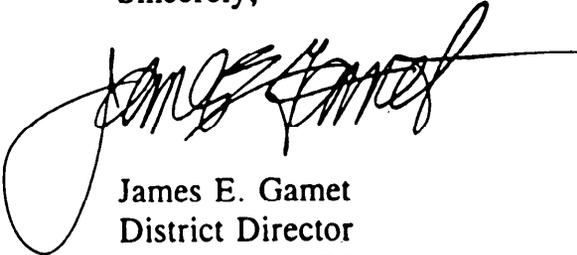
The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all warning letters 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 may include seizure and/or injunction.

We have received Mr. Paul M. William's comments of January 27, 1997. His comments have become part of the official file. You should notify this office in writing, within 15 working days of receipt of this letter, of the 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 15 working days, state the reason for this delay and the time within which the corrections will be completed.

Your response should be directed to Rebecca A. Asente, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana, 70122-3848, telephone number (504) 589-7166. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the agency staff, do not hesitate to contact Ms. Asente.

Sincerely,



James E. Gamet
District Director
New Orleans District

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Enclosure: FDA-483