



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFI-37  
Public Health Service  
Mid-Atlantic Region D1096B

Telephone (201) 331-2906

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

January 14, 1997

WARNING LETTER

RELEASE

REVIEWED BY: DCE  
C.O. 1/16/97  
DATE

Satish Patel, President and CEO  
Medisol Laboratories, Inc.  
46 DeForest Ave.  
East Hanover, New Jersey 07936

File No: 97-NWJ-16

Dear Mr. Patel:

This is regarding an inspection of your facility located at 46 DeForest Avenue, East Hanover, New Jersey between the dates of December 2 and 13, 1996. During the inspection our investigator documented serious deviations from the Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Parts 210 & 211) in conjunction with your firm's manufacture, processing, packing, and holding of Albuterol Metered Dose Inhaler (MDI), 90mcg/inhalation.

These deviations were noted on the FDA-483 presented to your firm at the close of the inspection on December 13, 1996. These CGMP deficiencies 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 significant observations are as follows:

Out of specification laboratory results for four Albuterol Aerosol MDI validation batches were invalidated without sufficient data to support conclusions, such as poorly trained analysts and equipment related problems.

Unidentified HPLC peaks found during stability testing of the biobatch (801-0008) and validation lots (801-0022, 801-0023, 801-0024) were not identified or evaluated. Individual levels were observed as high as 2.4%, 1.8% and 1.5%.

The TLC method used for testing impurities in the Albuterol drug substance and finished product on stability has not been shown to be capable of detecting and quantifying all impurities.

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HPLC peaks observed during a valve extractable study of Albuterol Aerosol MDI samples and empty cans filled with P-11(freon) were not identified or evaluated. In addition, the HPLC method used for the extractable study was not capable of detecting several of the known extractables provided by the vendor.

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 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. Possible actions include seizure and/or injunction.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific 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 the delay and the time needed to complete the corrections.

Please submit your response to Attention: Diane Edson,  
Compliance Officer, Food and Drug Administration, 10 Waterview  
Blvd., 3rd Floor, Parsippany, New Jersey 07054.

Sincerely,

  
JOANN M. GIVENS  
Acting District Director  
New Jersey District

CERTIFIED MAIL -  
RETURN RECEIPT REQUESTED

DCE:np