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DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE

Food and Drug Administration
Denver District Office
Building 20 - Denver Federal Center
P. O. Box 25087
Denver, Colorado 80225
TELEPHONE: 303-236-3000

April 7, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Thomas W. Bader
Owner
College Pharmacy
833 North Tejon Street
Colorado Springs, Colorado 80903

DEN-99-06

Dear Mr. Bader:

This letter is in reference to the prescription drug, Riboflavin Injection, your pharmacy prepared in July 1997 for [redacted]. This drug was administered intravenously to two patients who were subsequently hospitalized after experiencing septicemia.

Our laboratory analysis of this drug from an intact vial confirmed the presence of Pseudomonas aeruginosa, a gram-negative bacteria, as well as a bacterial endotoxin level greater than 1,250 Endotoxin Units (EU) per milligram of riboflavin. Analysis of one of the intravenous bottles to which the Riboflavin Injection had been added and which had been administered to one of the patients was also found to contain Pseudomonas aeruginosa.

These Riboflavin Injection products are adulterated under Section 501(a) (1) and 501(b) of the Federal Food, Drug and Cosmetic Act (the Act), in that they consisted in whole or in part of any filthy, putrid, or decomposed substance, and that they were represented as a drug the name of which is recognized in an official compendium and their quality or purity falls below the standards set forth in such compendium. These products are also misbranded under sections 502 (a) and (j) of the Act, in that their labeling is false and misleading, and that the products are dangerous to health when used in the dosage and manner and with the frequency and duration prescribed, recommended, or suggested in their labeling.

Riboflavin Injection is a drug recognized in the United States Pharmacopeia (the U.S.P.) as a sterile solution of Riboflavin in Water for Injection. It may not contain more than 7.1 U.S.P. Endotoxin Units (EU) per milligram of riboflavin and must meet the requirements under Sterility Tests. As stated above, your product is therefore adulterated as it was found to contain Pseudomonas aeruginosa and endotoxins greater than 1,250 EU per milligram.

The Food and Drug Administration considers these deviations to be serious violations. This list 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 Act.

You should take prompt action to prevent further contamination of the riboflavin injection products compounded by College Pharmacy. Failure to promptly take corrective action may result in regulatory action such as seizure and/or injunction without further notice. This letter does not represent a comprehensive review of all the products your firm distributes. It is your responsibility to ensure that all the drug products you distribute are in compliance with the requirements of the Act and regulations promulgated thereunder.

We request that you reply within fifteen (15) working days of your receipt of this letter, stating the specific action(s) you have taken to correct the violations. Your reply should be sent to the Food and Drug Administration, Denver District Office, Building 20 - Denver Federal Center, P.O. Box 25087, Denver, Colorado 80225, Attention: Regina A. Barrell, Compliance Officer.

Sincerely,

Gary C. Dean
District Director

cc: [XXX]

PURGED

Colorado State Board of Pharmacy
1560 Broadway, Suite 1310
Denver, Colorado 80202