



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFI-35 d1525b
Public Health Service

Food and Drug Administration
1141 Central Parkway
Cincinnati, OH 45202

November 6, 1996

WARNING LETTER
CIN-WL-97-1

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

John McNamara, CEO
Amerisource Corporation
300 Chester Field Parkway
Malvern, PA 19355

Dear Mr. McNamara:

During a 9/10-16/96 inspection of your drug repackaging operation at AmeriSource Health Services Corporation, located at 2550 John Glenn Avenue, Suite A, Columbus, Ohio, our investigator documented serious deviations from the Current Good Manufacturing Practices Regulations (Title 21 Code of Federal Regulations, Part 211). These 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.

Specific observations made during the Inspection include but are not limited to:

- (1) Failure to establish adequate procedures for control of labels and labeling to assure no label mix-ups occur. For example: labels and inserts are not maintained under controlled access; inserts are not stored physically separated; approved inserts/outserts are not identified in the master production records; master production records included two different labels as the approved labels; there are no written procedures nor documentation to assure proper inserts/outserts are used and discarded overpack labeling is not rendered unusable before discarding.
- (2) Failure to adequately perform or document training of personnel as required by written standard operating procedures. For example: no training documentation exists for three production personnel or any of the second shift QA personnel and QA training was provided by an employee who had just received the training.
- (3) Failure to adequately clean, document, and verify the adequacy of cleaning of packaging rooms and equipment between production runs. For example: no documentation exists for cleaning or inspection of rooms and equipment for at least nine batches of product and observation of cleanup procedures, on 9/11/96, revealed inappropriate cleanup procedures were being employed.

- (4) Failure to establish written master production and control records for the (overpack-blister pack) packaging lines.

The above described violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that you adhere to all current regulations applicable to your operations. 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 violations. Failure to achieve prompt correction may result in regulatory action without further notice. This includes seizure and/or injunction.

We have received a written response to the FDA-483, Inspectional Observations, issued at the conclusion of the subject inspection. This response letter, dated 10/15/95, was received from Greg Zurlage, President of AmeriSource Health Services. Based upon our review, this response appears to adequately address all of the above listed deviations as well as other objectionable observations listed on the FDA-483. The adequacy of your corrections will be verified during the next scheduled inspection.

If you have any questions regarding this letter, you should address these to the U.S. Food and Drug Administration, 1141 Central Parkway, Cincinnati, Ohio 45202-1097, to the attention of Charles S. Price, Compliance Officer, telephone (513) 684-3501 extension 165.

Sincerely,

John R. Marzilli
John R. Marzilli
District Director
Cincinnati District

cc: Gregory J. Zurlage, President
AmeriSource Health Services Corp.
2550 John Glenn Ave., Suite A
Columbus, OH 43217