



DEPARTMENT OF HEALTH & HUMAN SERVICES

94853d  
Food and Drug Administration

June 15, 2004

Chicago District  
550 West Jackson Blvd., 15th Floor  
Chicago, Illinois 60661  
Telephone: 312-353-5863

**WARNING LETTER**  
**CHI-15-04**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. David W. Bernauer  
CEO and Chairman of the Board  
Walgreen Co.  
200 Wilmot Rd.  
Deerfield, IL 60015

Dear Mr. Bernauer:

Inspection of your firm's warehouse at 5100 Lake Terrace N.E., Mt. Vernon, Illinois, by the Illinois Department of Public Health and the U.S. Food and Drug Administration (FDA) on February 25, 26, and 27, and March 2, 2004, documented numerous insanitary conditions which caused the food and drug products stored there to become adulterated.

Our inspection showed that the food and drug products stored and held at your facility violated the Federal Food, Drug, and Cosmetic Act (the Act), rendering them adulterated. These adulterated food and drug products: a) consisted in whole or in part of filthy substances, including rodent fecal pellets, rodent hair, and insects, in violation of Section 402(a)(3) of the Act [21 U.S.C. 342(a)(3)]; and/or b) had been held under insanitary conditions whereby they have become contaminated with rodent filth, in violation of Sections 402(a)(4) and 501(a)(2)(a) of the Act [21 U.S.C. 342(a)(4), 351(a)(2)(a)].

Evidence of rodent activity documented throughout the "old" and "new" warehouse included dead mice in traps, excreta pellets, and gnawed paper material observed in, on, and near food and drugs stored in the warehouse. Rodents gnaw holes were observed into several packaged food products with rodent hairs at gnaw holes into products. Many more fecal pellets were on food and drug packages and still more were found near the stored foods, drugs, and cosmetics in the warehouse.

Other conditions observed during the inspection that could be contributing factors to rodent infestation include damaged and/or poorly fitting rail and truck dock doors, gaps around a conduit entry into the building, and the structural condition of the concrete and expansion gaps at floor/wall/support beam junctions in various areas of the warehouse allowing the entry or harborage of pests. Additionally, the investigators observed cobwebs, dead insects, dust, debris, product spillage, and papers in the warehouse, indicating a general lack of good sanitation practices.

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Also, products that contain or may contain animal protein prohibited ruminant feed (BSE material) failed to bear the caution statement, "Do not feed to cattle or other ruminants." Specifically, pet food products were salvaged, repackaged, and donated to [REDACTED] and other similar organizations in the area, without the proper labeling and agreement that they would not be used for ruminants. Please refer to Title 21, Code of Federal Regulations, Section 589.2000, concerning these requirements.

Our laboratory confirmed the findings of rodent excreta, rodent hairs on product gnaw holes, and rodent gnawed fibers (packaging material) sampled from the warehouse during the inspection.

The above listed violations are not intended to be all-inclusive. It is your responsibility to assure adherence with each requirement of the Act and its implementing regulations. The investigators reported that you destroyed food products that showed evidence of contamination and began to take some steps to correct the insanitary conditions in your facility. We request that you take prompt action to correct all violations.

Please provide this office, within 15 working days of receipt of this letter, a detailed response stating the actions you plan to take and have taken to correct and prevent the recurrence of these objectionable conditions. Provide the time within which corrections will be completed, reasons why any corrective action cannot be completed, and documentation to show that corrections have been made. Failure to take prompt action to correct all violations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

Your reply should be directed to Paul A. Boehmer, Compliance Officer, at the Chicago District Office.

Sincerely,



Scott J. MacIntire  
District Director

cc: Stephen J. Lawrence,  
Distribution Center Manager  
Walgreen Co.  
5100 Lake Terrace NE  
Mount Vernon, IL 62864-9665