



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

m2753v

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDEX

WARNING LETTER

June 30, 1999

Our Reference: 2938471

Owen Lin, President
American Bantex Corporation
1640 Rollins Road
Burlingame, CA 94011

Dear Mr. Lin:

On June 18, 1999, our review of the entry documents for [REDACTED] cartons of vinyl patient examination gloves offered into import into the United States by your firm under ABI entry number AK5-0023424-5 revealed the entry consisted of vinyl patient examination gloves manufactured by two firms, [REDACTED] and [REDACTED]. Your ABI (electronic) entry only declared one manufacturer, [REDACTED]. In addition, the vinyl patient examination gloves were entered into the ABI system with product code 80 LYY, latex patient examination gloves. Vinyl patient examination gloves manufactured by [REDACTED] are subject to Import Alert #80-04.

Such misrepresentation at the time of entry appears to be an attempt to circumvent our Automatic Detention action, initiated in response to a history of adulterated vinyl examination gloves manufactured by [REDACTED], as covered by Import Alert #80-04 (copy enclosed). Such circumvention is a violation of the Federal Food, Drug, and Cosmetic Act, (21 USC. 331 et seq.) and may violate other provisions of the law, such as 19 U.S.C. 1592 and 18 U.S.C. 542.

Failure to prevent future violations may result in regulatory action, without further notice, such as seizure of, or injunction against, future shipments. It is your responsibility, as the importer, to ensure that importation of products is conducted in full compliance with the requirements of the Federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder.

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Please notify this office in writing, within 15 days of receipt of this letter, of the specific steps you have taken to prevent recurrence of the noted violations. Your written reply should be addressed to the Food and Drug Administration, Attention: Mr. Russell A. Campbell, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, CA 94502.

Sincerely,

A handwritten signature in black ink, appearing to read "Patricia C. Ziobro" followed by a flourish.

Patricia C. Ziobro
Director
San Francisco District

Enclosure