



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
San Francisco District

1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: (510) 337-6700

FAX: (510) 337-6701

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

September 23, 1997

Our Reference: 2437064

Sunny Hew, President
Regaltex International, Inc.
22-B Cragwood Road
Avenel, NJ, 07001

WARNING LETTER

Dear Mr. Hew:

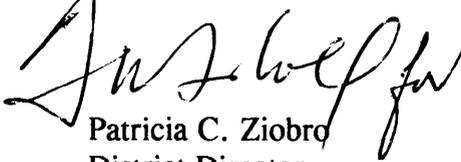
On August 29, 1997, our inspector visited [REDACTED] located at [REDACTED] to verify that a shipment of latex examination gloves, imported into the United States by your firm on August 8, 1997, under Customs entry and FDA OASIS sample number AR3-0014122-3, had been held intact while under detention. A portion of the shipment was distributed. This is a violation of Title 21, Code of Federal Regulations, Section 1.90, which requires the importer to hold an entry intact pending receipt of a May Proceed or Release Notice from FDA. We are hereby issuing a Redelivery for FDA Examination Requested (copy attached) for the portion of the above referenced shipment that had been distributed.

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice, such as seizure, injunction, or a continuation of the automatic detention of future shipments. It is your responsibility as the importer to ensure that the imported products meet all the requirements of the Federal Food, Drug, and Cosmetic Act, and the regulations promulgated thereunder.

Please notify this office in writing within 15 working days after receipt of this letter of the specific steps you have taken to correct the violation, including the explanation of each step being taken to prevent recurrence.

Your written reply should be addressed to the U.S. Food and Drug Administration, attention George R. Richards, Acting Compliance Officer, Team 13, 1431 Harbor Bay Parkway, Alameda, California 94502-7070.

Sincerely,

A handwritten signature in black ink, appearing to read "Patricia C. Ziobro". The signature is fluid and cursive, with a large initial "P" and "Z".

Patricia C. Ziobro
District Director

attachment: Redelivery for FDA Examination Requested