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**DEPARTMENT OF HEALTH AND HUMAN SERVICES** HEE-35

**Public Health Service  
Food and Drug Administration  
New York District Office  
850 Third Avenue  
Brooklyn, NY 11232-1593**

**Telephone: [718] 340-7000 ext. 5301**

**WARNING LETTER**

**August 4, 1998**

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

Mr. Francisco Perez  
86 Fort Washington Avenue  
Apartment 5-J  
New York, NY 10032

**Ref: 35-NYK-98**

Dear Mr. Perez:

The Food and Drug Administration (FDA) has information which shows that your firm violated the Federal Food, Drug and Cosmetic Act.

On ~~March~~ <sup>March</sup> 11, 1998, we sampled a shipment of cheese, which your firm imported into the United States on March 10, 1998, under an informal entry filed by Highgrace International. The two cheeses in this entry were sampled by the FDA at [REDACTED], under entry number I99-2036254-0. Our examination of these cheeses found them to be made from unpasteurized milk, and to lack the mandatory English labeling. On May 8, 1998, a Notice of Detention and Hearing was issued to you as importer. Then, on June 2, 1998, after receiving no response to the detention, a Notice of Refusal of Admission was issued, requiring export or destruction under the supervision of U.S. Customs.

Our contact with your broker, Highgrace International, on July 1, 1998, indicated that this cheese has been sold by you. This is a violation of 21 CFR 1.90, which requires the importer to hold an entry intact pending receipt of a May Proceed or Release Notice from FDA.

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

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**Mr. Francisco Perez**

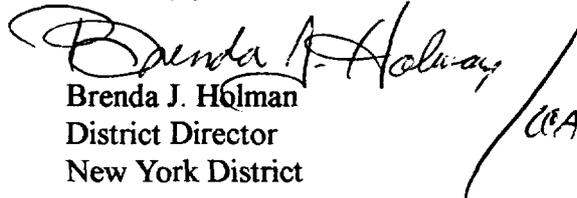
Within 15 working days of receipt of this letter, notify this office in writing of the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent the recurrence of the violation.

A copy of this letter, except for any confidential, personal, or commercial information will be placed on public display no earlier than fifteen (15) days after the date of this letter. Your response will be on public display with any confidential, personal or commercial information purged.

Your written reply should be addressed to the attention of Kenneth M. Klein, Compliance Officer at:

Food and Drug Administration  
850 Third Avenue  
Brooklyn, NY 11232-1593

Sincerely yours,

  
Brenda J. Holman  
District Director  
New York District

cc: Mr. Persio Rodriguez  
Highgrace International  
133-40 Lefferts Blvd.  
South Ozone Park, NY 11420